#### IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF ALABAMIAVE DE EASTERN DIVISION

2007 JUL 19 P 3: 50

**SUE F. BRADLEY,** 

Plaintiff,

VS.

**GUIDANT CORPORATION, GUIDANT SALES** CORPORATION, DR. MICHAEL AIKENS, JOE NAPIER, JEFF HALL, TAB WHISENHUT, LINDA **GARMON** and Sales representatives, and Fictitious Defendants A, B, C, D, E, F, being those Persons, Sales Representatives Firms or Corporations whose acts, omissions, negligence and/or other wrongful conduct caused or contributed to the Plaintiff's Injuries and whose true names and Identities are presently unknown to the Plaintiff but will be substituted by amendment when ascertained,

Defendants.

DEBRA P. HACKETT, CLK U.S. DISTRICT COURT MIDDLE DISTRICT ALA

# CIVIL ACTION NO. B. M-CV-labl-MHT

(removed from the Circuit Court of Randolph County, Alabama, CV-07-85)

# NOTICE OF REMOVAL BY DEFENDANTS GUIDANT CORPORATION AND GUIDANT SALES CORPORATION

Defendants Guidant Corporation and Guidant Sales Corporation ("Defendants"), pursuant to the provisions of 28 U.S.C. § 1441(a) and (b) and 28 U.S.C. § 1446, file this Notice of Removal of this cause from the Circuit Court of

Randolph County, Alabama, to the United States District Court for the Middle District of Alabama, Eastern Division. In support of this Notice of Removal, Defendants state as follows:

#### **Introductory Statement**

This action is one of over 1,860 products liability actions against Defendants that have recently been filed in or removed to federal courts. As a result of these numerous suits, on November 7, 2005, pursuant to 28 U.S.C. §1407, the Judicial Panel on Multi-District Litigation entered a transfer order establishing an MDL entitled *In re Guidant Corp. Implantable Defibrillators Products Liability Litigation*, MDL-1708, and transferring and consolidating a number of cases to the United States District Court, District of Minnesota ("MDL Court"). More than 1,800 cases are currently pending in the MDL, and many more are in the process of being transferred to the MDL. Once removed, Defendants intend to immediately seek inclusion of the instant case in the MDL proceeding, and intend to file a motion to stay this case pending MDL transfer.<sup>2</sup>

On June 20, 2007, Plaintiff filed this action against Defendants asserting personal injury claims allegedly resulting from the implantation of a Guidant

Pursuant to Rule 7.5(e) of the Rules of Procedure for the JPML, Defendants intend to immediately notice this case to the Clerk of the Panel as a "tag-along action."

A true and correct copy of the transfer order establishing MDL 1708 and transferring a number of cases to the District Court of Minnesota is attached hereto as Exhibit A.

Insignia Entra Model 1294 pacemaker ("device"). Just as in the scores of other actions filed against Defendants, Plaintiff has asserted numerous product liability causes of action including strict liability, negligence, and breach of express and implied warranty. Plaintiff also asserts causes of action for fraud and conspiracy. Each of Plaintiff's allegations, like the allegations in MDL-1708, is based on the premise that a cardiac device manufactured by Defendants was defective. In addition to the numerous claims asserted against Defendants, however, Plaintiff also asserts claims against Dr. Michael Aikens and four sales representatives, Jeff and Linda Garmon (the Nappier, Tab Whisenhunt Hall. Joe representatives"). The joinder of these non-diverse parties is a clear attempt to keep this action out of federal court and away from the above-referenced MDL proceedings. This case is removable, however, because complete diversity exists between Plaintiff and all properly-joined defendants.

#### **Notice of Removal**

1. On June 20, 2007, Plaintiff filed this action against Guidant Corporation, Guidant Sales Corporation, Dr. Michael Aikens, and sales representatives Joe Nappier, Jeff Hall, Tab Whisenhunt, and Linda Garmon.<sup>3</sup> A true and correct copy of the Summons and Complaint served on Defendants and

<sup>&</sup>lt;sup>3</sup> Joe Nappier and Tab Whisenhunt's names are misspelled in the Complaint.

the complete contents of the state court file are collectively attached hereto as Exhibit B. The action is styled as Sue F. Bradley vs. Guidant Corporation, Guidant Sales Corporation, Dr. Michael Aikens, Joe Napier, Jeff Hall, Tab Whisenhut, Linda Garmon and Sales representatives, and Fictitious Defendants A, B, C, D, E, F, being those Persons, Sales Representatives, Firms or Corporations whose acts omissions, negligence and/or other wrongful conduct caused or contributed to the Plaintiff's Injuries and whose true names and Identities are presently unknown to the Plaintiff but will be substituted by amendment When ascertained, in the Circuit Court of Randolph County, Alabama.

2. On June 21, 2007, Dr. Michael Aikens was served with Plaintiff's Complaint, and was the first pleading received by any defendant setting forth the claims for relief on which this action is based. Guidant Corporation was served on June 27, 2007. Guidant Sales Corporation was served on June 27, 2007. Linda Garmon was served on July 3, 2007. Upon information and belief, Tab Whisenhunt, Joe Nappier and Jeff Hall have not been served at the time of removal. Defendants file this Notice of Removal within 30 days of service of the initial pleadings, and within one year of the commencement of this action as required by 28 U.S.C. § 1446(b). Accordingly, removal of this action is timely. No previous application for removal has been made.

- 3. The United States District Court for the Middle District of Alabama, Eastern Division, embraces the county in which the state court action is now pending, and thus, this Court is the proper venue for this action pursuant to 28 U.S.C. § 81(b)(3).
- 4. This suit is an action of which this Court has original jurisdiction under the provisions of 28 U.S.C. § 1332, and is one that may be removed to this Court under the provisions of 28 U.S.C. § 1441. Removal under section 1441 is appropriate in that there exists complete diversity of citizenship between Plaintiff and all *properly joined* Defendants in the underlying cause, and the amount in controversy exceeds \$75,000, exclusive of interest and costs.
  - 5. Plaintiff is a citizen of Alabama. See Complaint at  $\P$  3.
- 6. Guidant Corporation is a foreign corporation. Guidant Corporation is an Indiana corporation with its principal place of business in Indianapolis, Indiana. Thus, pursuant to 28 U.S.C. § 1332(c)(1), Guidant Corporation is a citizen of Indiana.
- 7. Guidant Sales Corporation is a foreign corporation. Guidant Sales Corporation is an Indiana corporation with its principal place of business in Indianapolis, Indiana. Thus, pursuant to 28 U.S.C. § 1332(c)(1), Guidant Sales Corporation is a citizen of Indiana.

- 8. Defendants Dr. Michael Aikens, Joe Nappier, Jeff Hall, Tab Whisenhunt, and Linda Garmon are citizens of Alabama. The fact that there is a lack of complete diversity on the face of the Complaint is, however, irrelevant for removal purposes. *See Legg v. Wyeth*, 428 F.3d 1317, 1321 (11th Cir. 2005).
- 9. 28 U.S.C. § 1441(b) states that suits that do not arise under federal law are removable "if none of the parties in interest *properly* joined and served as Defendants is a citizen of the State in which such action is brought." (emphasis added).
- 10. Non-diverse Defendants Dr. Michael Aikens, Joe Nappier, Jeff Hall, Tab Whisenhunt, and Linda Garmon have not been properly joined. Their inclusion in this action is for the sole purpose of preventing Defendants from exercising their right to remove this case to federal court. Accordingly, their non-diverse status is irrelevant for the purposes of removal analysis.
- 11. It is well-settled law that "diversity jurisdiction 'cannot be defeated by a fraudulent joinder of a resident defendant having no real connection with the controversy." *Bloodsworth v. Smith & Nephew*, 2005 WL 3470337, at \*3 (M.D. Ala. Dec. 19, 2005) (*quoting Wilson v. Republic Iron & Steel Co.*, 257 U.S. 92, 97 (1921)). Removal of this suit pursuant to complete diversity of citizenship should not be thwarted by Plaintiff's attempt to join Dr. Michael Aikens and Joe Nappier, Jeff Hall, Tab Whisenhunt, and Linda Garmon improperly in order to

destroy diversity. As the Supreme Court has stated, "the Federal courts should not sanction devices intended to prevent a removal to a Federal court where one has that right, and should be equally vigilant to protect the right to proceed in the Federal court . . " Wecker v. Nat'l Enameling & Stamping Co., 204 U.S. 176, 186 (1907).

- 12. Under Eleventh Circuit law, fraudulent joinder can be established in one of three ways:
  - (1) when there is no possibility that the plaintiff can prove a cause of action against the resident (non-diverse) defendant, or (2) when there is outright fraud in the plaintiff's pleading of jurisdictional facts, or (3) where a diverse defendant is joined with a nondiverse defendant as to whom there is no joint, several or alternative liability and where the claim against the diverse defendant has no real connection to the claim against the nondiverse defendant.

Triggs v. John Crump Toyota, Inc., 154 F.3d 1284, 1287 (11th Cir. 1998).

13. Here, "there is no possibility" that Plaintiff can prove any of her claims against Dr. Aikens, Mr. Nappier, Mr. Hall, Mr. Whisenhunt or Ms. Garmon. Plaintiff, in order to meet her burden, must provide a possibility of liability that is "reasonable, not merely theoretical, and, in considering *possible* state law claims, possible must mean more than such a possibility that a designated residence can be hit by a meteor tonight." *Bloodsworth*, 2005 WL 3470337, at \*4 (*quoting Legg*,

428 F.3d at 1325 n.5) (internal quotation marks omitted). Plaintiff cannot possibly meet this burden.

#### The sales representatives are fraudulently joined

- 14. Plaintiff's Complaint fails to state any claim under which there is a "reasonable basis" to impose Alabama state-law liability on the sales representatives. As such, the non-diverse status of these defendants should be ignored for the purposes of determining whether removal is proper. *See Legg*, 428 F.3d at 1321. In her Complaint, Plaintiff asserts claims of strict liability (Count I), products liability (Count III), negligence (Count IV), breach of express (Count V) and implied warranties (Count VI), misrepresentation, fraud, suppression and deceit (VII), and civil conspiracy (Count VIII) against the sales representatives. The sales representatives' only connections to this case are that they were Company sales representatives who allegedly serviced the pacemaker in question and distributed CPI devices in Alabama.<sup>4</sup> Their roles as sales representatives create no "reasonable basis" for the imposition of legal liability under any of the claims pleaded by Plaintiff.
- 15. The first and third claims alleged against the sales representatives are for strict liability. Plaintiff asserts that the sales representatives

<sup>&</sup>lt;sup>4</sup> It should be noted that Ms. Garmon, Mr. Hall and Mr. Whisenhunt did not work in the area where Dr. Aikens practices.

are strictly liable because they "designed, manufactured, tested, marketed, distributed, implanted, promoted and sold" the pacemaker at issue in this case. See Additionally, Plaintiff alleges that these products were Complaint at  $\P$  48. unreasonably dangerous and defective." Id. at ¶ 49. In their attached declarations, the sales representatives all state that they had no responsibility for the design, development, manufacturing or warnings accompanying the device in question. See Declarations of Jeff Hall, Joe Nappier, Tab Whisenhut and Linda Garmon at ¶¶ 4-5, attached hereto as Exhibits C, D, E and F. Additionally, Plaintiff alleges that the pacemaker in question was "unaltered." Complaint at ¶ 50. This allegation, coupled with the sworn statements by the sales representatives that they had no responsibility for the design, development, manufacturing, or warnings and that they never "knowingly made a misrepresentation about the safety or efficacy" of the device, establishes that there is no "reasonable basis" for imposing liability upon these Defendants. See Exhibits C, D, E and F, at ¶¶ 4, 5, 7. the Supreme Court of Alabama has adopted the learned-intermediary doctrine,<sup>5</sup> which provides that, "any duty to warn is owed by [the manufacturer] to the surgeon who performed [the] procedures...the duty is not owed by [the sales representative.]" Bloodsworth, 2005 WL 3470337, at \*7; see also Catlett v. Wyeth, Inc., 379 F. Supp.2d 1374, 1381 (M.D. Ga. 2004) (there is "no basis for a claim

<sup>&</sup>lt;sup>5</sup> See Morguson v. Baxter Healthcare Corp., 857 So.2d 796 (Ala. 2003).

against a sales representative under the learned intermediary doctrine ... [a]lthough the manufacturers employ the sales representatives to be one source of that information, the manufacturers are the ones who are ultimately responsible and thus liable...for any alleged failure to provide information.").

Plaintiff next alleges that the sales representatives "had a duty 16. to exercise reasonable care in the manufacture, sale and/or distribution of" the pacemaker at issue. See Complaint at ¶ 73. For a sales representative to be "personally liable for the negligent acts of the corporation, 'there must have been upon his part such a breach of duty as contributed to, or helped bring about, the injury; that is to say, he must be a participant in the wrongful act." Legg, 428 F.3d at 1324 (quoting Crigler v. Salac, 438 So.2d 1375, 1380 (Ala. 1983)). In other words, the sales representative must have "personally participate[d] in the tort." See Turner v. Hayes, 719 So.2d 1184, 1188 (Ala. Civ. App. 1997). Plaintiff has not presented evidence that the sales representatives knew or should have known of any alleged defect in the device in question. Conversely, the sales representatives, in their declarations, state that they did not participate in the design, development, or manufacturing of the device and that they have never knowingly made a misrepresentation about the safety or efficacy of the device. See Exhibits C, D, E and F, at ¶¶ 4, 5, 8. Therefore, these Defendants did not "personally participate" in any alleged tort and there is no "reasonable possibility" that they will be found liable under Alabama negligence law.

The next two claims in Plaintiff's - breach of express and 17. implied warranties – likewise present no "reasonable basis" for imposing liability on the sales representatives. Under Alabama law, a breach-of-warranty claim is only viable against the "seller" of the goods. See ALA. CODE §§ 7-2-313(1)--7-2-315(1) (warranty claims require a "seller" to create the warranties). A sales representative does not fit the definition of a "seller." Bloodsworth, 2005 WL 3470337, at \*6. In Bloodsworth, although discussing "seller" in terms of the Alabama Extended Manufacturer's Liability Doctrine, the court determined the sales representative in that case was excluded from the definition of "seller." The Bloodsworth sales representative "merely received orders and delivered...products, in their original sealed packages, to physicians, and had no knowledge of any Bloodsworth, 2005 WL 3470337, at \*7. design or manufacturing defect." Additionally, the sales representative did not have "any significant control over the distribution of...products [nor] could have prevented, in any substantial way, ...dispersion of its products." Bloodsworth, 2005 WL 3470337, at \*6. Thus, the Bloodsworth court concluded the sales representative in that case was not a "seller." Here, the sales representatives do not fit the definition of a "seller" for the These four fraudulently-joined Defendants have no "significant same reasons.

control over the distribution" or dispersion of CPI's devices. Therefore, they are not "sellers" and cannot be liable for breach of express or implied warranty under Alabama law.

- 18. Next, Plaintiff alleges that the sales representatives' "misrepresentation and suppressions of material facts were done intentionally, willfully, and/or negligently" with the intent to induce Plaintiff's purchase. *See* Compl at ¶¶90, 91. In their declarations, the sales representatives all make sworn statements, however, that they did not knowingly make a misrepresentation about the pacemaker in question. *See* Exhibits C, D, E and F at  $\P$ 8.
- "a demonstration of bad faith. negligent 19. Absent untenable against pharmaceutical sales misrepresentation claim is a representative." Bloodsworth, 2005 WL 3470337, at \*8. Furthermore, "those who are only conduits through which faulty information is supplied by one person to a third person cannot be held liable for fraud unless they acted in bad faith." Legg, 428 F.3d at 1324 (quoting Fisher v. Comer Plantation, Inc., 772 So.2d 455 (Ala. 2000)). Plaintiff here has not presented evidence of bad faith. Conversely, the sales representatives have sworn that they did not make representations in bad faith and accordingly, there is no "reasonable basis" for liability with regard to this claim.

¶ 93. Under Alabama law, a claim of conspiracy requires an "underlying tort." See, e.g., Holman v. Childersburg Bancorporation, 852 So. 2d 691 (Ala. 2002). As set forth above, Plaintiff has no viable underlying claim against the sales representatives. As such, there is no reasonable basis for a conspiracy claim against the sales representatives.

#### Dr. Aikens is fraudulently joined

- 21. Plaintiff alleges that Dr. Aikens implanted the subject pacemaker in her on or about September 22, 2004. *See, e.g.,* Complaint ¶ 3. Plaintiff does not allege that Dr. Aikens manufactured, designed, tested, labeled, warranted, or sold the pacemaker at issue. *See generally* Complaint.
- 22. In a products liability action involving a prescription medicine or medical device, a resident physician is fraudulently joined when, as here, conclusory allegations of the physician's knowledge are contradicted by specific allegations that the manufacturer defendant concealed information from the general public, including health care providers. *See In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 295 (S.D.N.Y. 2001) (Alabama resident physician was fraudulently joined in products liability action against manufacturer of prescription medication, where plaintiffs' specific allegations that the manufacturer misrepresented and concealed material facts about the safety and efficacy of its

drug refuted the assumption that the physician had knowledge of the drug's harmful effects); *Spier v. Bayer Corp.* (*In re Baycol Prods. Litig.*), 2003 WL 21223842, at \*2 (D. Minn. May 27, 2003) (plaintiff's conclusory allegation that resident physician "knew or should have known" of drug's risks was insufficient to defeat a finding of fraudulent joinder, where the "main thrust" of the action was that the manufacturer defendants had misrepresented the drug's risks and failed to adequately warn of such risks).

- 23. Put another way, "in light of plaintiff's myriad allegations that the defendants withheld information concerning the risks of [a prescription medication] from physicians . . . an entirely conclusory allegation that the physician failed to warn of risks of [that medication] is insufficient" to provide a basis for recovery against the non-diverse defendant. *In re Rezulin Prods. Liab. Litig.*, No. 00 CIV 2843 (LAK), MDL No. 1348, Pretrial Order No. 122, slip op. at 1 (Jan. 6, 2003) (attached hereto as Exhibit G).
- 24. That is precisely the case here. Plaintiff's Complaint includes "myriad allegations" that Guidant misrepresented and concealed the risks associated with its devices from both patients and physicians.<sup>6</sup> For example, Plaintiff alleges as follows:

<sup>&</sup>lt;sup>6</sup> The fact that each count of the Complaint is pleaded generally against all "Defendants" does not defeat fraudulent joinder where it is evident from the context that the claims cannot be

- a. "The Guidant Defendants have engaged in a pattern and practice of deception concerning their implantable cardiac devices."
- b. "For example, on May 24, 2005, the New York Times reported that for three years Guidant concealed from doctors and others that its [products] contained a flaw. . ."
- c. "Guidant changed its manufacturing processes twice in 2002 (April and November) to address this defect but concealed this fact from doctors..."
- d. "[Defendants] [flailed to provide adequate training to medical care providers..."
- e. "[Defendants] [flailed to warn physicians ... about the following: (1) about the need for comprehensive, regular medical monitoring to ensure early discovery of potentially fatal breakage; (2) the danger of breakage; (3) the dangers of the consequences of breakage; (4) proper installation of the devices:"

referring to the physician defendant, Dr. Aikens. See, e.g, Badon v. R J R Nabisco, Inc., 224 F.3d 382, 391-93 (5th Cir. 2000). Here, although all counts except for Count II contain allegations against "Defendants" generally, it is clear from the context that they are directed solely to the medical device company defendants, and not to Dr. Aikens.

- f. "Defendants have made and some continue to make false and fraudulent misrepresentations to ... physicians..."
- g. "Defendants ... fraudulently deceived the physicians ..."
- h. "Plaintiff and her physician reasonably relied upon the skill and judgment of said Defendants..."

Complaint,  $\P$  ¶ 2, 74, 88, 89, and 90.

- Plaintiff does not allege, however, that Guidant had disclosed 25. any alleged defects to Dr. Aikens, or that he otherwise had this knowledge, by or prior to September 22, 2004, when the allegedly defective product was installed.
- Therefore, the conclusory allegations that Dr. 26. proximately caused any injury to Plaintiff by negligently implanting or removing the product at issue, juxtaposed with the claims that Guidant hid the risks and dangers allegedly associated with the use of its products from physicians prior to plaintiff's implantation, demonstrate that Dr. Aikens has been fraudulently joined.
- The United States District Court for the Northern District of 27. Alabama refused to remand plaintiffs' claims where plaintiffs made contradictory allegations that a pharmaceutical company concealed information from doctors and that doctors were negligent when not considering the allegedly concealed information when making prescription decisions. Wilkes v. Merck & Co., Inc., No. 05-RRA-1214-S, slip op. at 1 (N.D. Ala., June 30, 2005) (attached hereto as

Exhibit H). The Court stayed the case pending transfer to the Vioxx MDL, holding that "[b]ecause of the contradictory allegations against the physician defendants, and the failure of the complaint to comply with Alabama law concerning specificity in making allegations against physicians, it appears to be a good possibility that it will be determined that the individual defendants were fraudulently joined." *Id.* at 2-3.

28. The same is true in this case. Plaintiff repeatedly alleges that Guidant misrepresented or suppressed facts about its products from the public, including doctors, then also alleges, in wholly conclusory terms, that Dr. Aikens was negligent in implanting and removing those same products from plaintiff. These two statements are incompatible.

#### Dr. Aikens is fraudulently misjoined

- 29. Further, Plaintiff's claims against Dr. Aikens' are fraudulently misjoined with the claims against Guidant in an attempt to defeat removal. Therefore, the doctor's citizenship must be ignored for the purpose of determining the propriety of removal. *See, e.g., Tapscott v. MS Dealer Service Corp.*, 77 F.3d 1353, 1359-1360 (11th Cir. 1996), *abrogated on other grounds, Cohen v. Office Depot, Inc.*, 204 F.3d 1069 (11th Cir. 2000).
- 30. "Misjoinder may be just as fraudulent as the joinder of a resident defendant against whom a plaintiff has no possibility of a cause of action."

Tapscott, 77 F.3d at 1360. "Joinder of defendants under Rule 20 requires: (1) a claim for relief asserting joint, several, or alternative liability and arising from the same transaction, occurrence, or series of transactions or occurrences, and (2) a common question of law or fact." *Id.* (citing Fed. R. Civ. P. 20(a)).

- Aikens, the presence of those claims in this suit will not defeat diversity jurisdiction because the claims against the two defendants do not arise out of the same transaction, occurrence, or series of transactions or occurrences as required by Rule 20(a). See In re Rezulin Prods. Liab. Litig., 00 Civ. 2843, Pretrial Order No. 150, 2003 WL 21276425 at \*1-2 (LAK) (S.D.N.Y. June 2, 2003) (claims against non-diverse physician fraudulently misjoined with claims against drug manufacturer where basis of claim against physician was failure to diagnose alleged liver dysfunction, while basis of claim against manufacturer went "principally to the safety and efficacy of the drug and ha[d] little if anything to do with the malpractice claim.").
- 32. Where the claims against one defendant are "wholly distinct" from the claims against the other defendant, and the non-diverse defendant has "no real connection with the controversy" involving the diverse defendant, the requirements for joinder under Rule 20 have not been met. *See Tapscott*, 77 F.3d at 1360.

- 33. By tacking the claims against Plaintiff's physician onto his Complaint against Guidant, Plaintiff is attempting to rely on the unrelated claims against Dr. Aikens to evade federal jurisdiction. This Court should not permit Plaintiff to prevail on such an attempt to manipulate the removal statute. Where, as here, a plaintiff attempts to combine two completely unrelated claims in order to avoid federal jurisdiction, this "attempt to join these parties is so egregious as to constitute fraudulent joinder." *Tapscott*, 77 F.3d at 1360.<sup>7</sup> "A defendant's 'right of removal cannot be defeated by a fraudulent joinder of a resident defendant having no real connection with the controversy." *Id.* (quoting *Wilson v. Republic Iron & Steel Co.*, 257 U.S. 92, 97 (1921)).
- 34. Assuming the Court does not exercise jurisdiction over plaintiff's claims against Dr. Aikens, the Court nevertheless has jurisdiction over plaintiff's claims against Guidant. Additionally, the Court may sever and remand plaintiff's claims against Dr. Aikens. *See Alexander v. Boston Scientific, et al.*, No. 07-1129, Slip. Op at 14 (D. Minn, June 4, 2007) (severing and remanding malpractice claims against hospital while retaining product liability claims),

<sup>&</sup>lt;sup>7</sup> See also Koch v. PLM Int'l, Inc., No. Civ. A 97-0177-BH-C, 1997 WL 907917, \*4 (S.D. Ala. Sept. 24, 1997) (concluding that joinder of plaintiffs constituted fraudulent misjoinder because it reflected "glaring manipulation" and "transparent artifice to defeat the diversity jurisdiction of this court"); Lyons v. American Tobacco Co., No. Civ. A. 96-0881-BH-S, 1997 WL 809677, at \*4 (S.D. Ala. Sept. 30, 1997) (holding that "[d]efendants will not be deprived of their right to defend themselves in a federal forum through the sophistic pleadings of the plaintiffs" against cigarette manufacturers and distributors).

attached hereto as Exhibit I; *Rezulin*, 2003 WL 21276425 at \*1 (remanding fraudulently misjoined claim against non-diverse physician and otherwise denying motion to remand); *Lee v. Mann*, 2000 WL 724046 (Va. Cir. Ct. 2000) (granting a motion to sever a prescribing physician from a complaint against a pharmaceutical manufacturer because the two claims did "not arise out of the 'same transaction or occurrence'").

rise to a "reasonable basis" for liability as to Dr. Aikens or the sales representatives. Thus, Plaintiff's joinder of these Defendants can "only be characterized as a sham, at the unfair expense not only of [Guidant] but of many individuals and small enterprises that are being unfairly dragged into court simply to prevent the adjudication of lawsuits against [Guidant], the real target, in a federal forum." *Legg*, 428 F.3d at 1320 (*quoting Anderson v. Am. Home Prods. Corp.*, 220 F. Supp.2d 414, 425 (E.D. Pa. 2002). Therefore, pursuant to 28 U.S.C. § 1332, complete diversity of citizenship exists.

#### **Amount in Controversy**

36. Based on Plaintiff's allegations and the damages sought, the amount in controversy exceeds \$75,000, exclusive of interest and costs. Plaintiff has sued Defendants for strict liability, negligence, breach of express and implied

warranties, fraud and conspiracy arising from Plaintiff's use of a pacemaker that was allegedly designed, manufactured and supplied by Defendants. Plaintiff claims that her pacemaker failed prematurely and required several medical procedures.

- Plaintiff seeks an unspecified amount of compensatory and punitive damages in this case. Complaint, ¶94. Plaintiff claims to have suffered "severe chest pain and paroxysmal atrial fibrillation" as a result of the product at issue, and that two surgical procedures were required to remedy this situation. *Id.* at  $\P = 38$ , 41. Plaintiff claims that she "requires reasonable and necessary health care, attention and services, and did incur medical, health, incidental, and related expenses." *Id.* at  $\P = 92$ . Plaintiff further claims to have suffered economic loss and diminished earning capacity. *Id.* at  $\P = 62$ .
- 38. As set forth above, there are currently more than 1800 cases in the *In re Guidant Corp. Implantable Defibrillators Products Liability Litigation*, MDL-1708. These claims are substantially similar to the claims in this case, e.g., that cardiac devices manufactured by Defendants caused personal injury to plaintiffs implanted with these devices. Many of these cases were originally filed in state courts and removed to federal court, and many claimed unspecified

<sup>&</sup>lt;sup>8</sup> A demand for punitive damages must be included in the calculation of the amount in controversy. *Bell v. Preferred Life Assurance Soc'y*, 320 U.S. 238, 240 (1943).

compensatory and punitive damages.

- Moreover, products liability claims in Alabama routinely result 39. in verdicts in excess of \$75,000 exclusive of interest and costs. See, e.g., Exhibit J; see also Toole v. McClintock, 999 F.2d 1430 (11th Cir. 1993) (addressing on appeal an award of \$400,000 in compensatory damages and \$5,000,000 in punitive damages in a medical product liability case); Benford v. Richard's Medical Co., 792 F.2d 1537 (11th Cir. 1986) (discussing an award of \$165,000 in compensatory and \$100,000 in punitive damages in a medical product liability case). Thus, there is no question that the amount in controversy exceeds \$75,000, exclusive of interest and costs.
- As demonstrated above, this Court has original jurisdiction over 40. this action pursuant to 28 U.S.C. § 1332(a) because the amount in controversy, exclusive of interest and costs, exceeds the sum or value of \$75,000 and is between citizens of different states.
- A copy of this Notice of Removal is being served on Plaintiff 41. and filed with the Circuit Court of Randolph County, Alabama.
- If any question arises as to the propriety of the removal of this 42. action, Guidant requests the opportunity to present a brief and oral argument in support of its position that this case is removable.

WHEREFORE, Defendants give notice that the matter styled Sue F. Bradley vs. Guidant Corporation, Guidant Sales Corporation, Dr. Michael Aikens, Joe Napier, Jeff Hall, Tab Whisenhut, Linda Garmon and Sales representatives, and Fictitious Defendants A, B, C, D, E, F, being those Persons, Sales Representatives, Firms or Corporations whose acts omissions, negligence and/or other wrongful conduct caused or contributed to the Plaintiff's Injuries and whose true names and Identities are presently unknown to the Plaintiff but will be substituted by amendment when ascertained, in the Circuit Court of Randolph County, Alabama, is removed to the United States District Court for the Middle District of Alabama, Eastern Division and request that this Court retain jurisdiction for all further proceedings.

Respectfully submitted,

Andrew B. Johnson (JOH168) One of the attorneys for Defendants

Guidant Corporation and Guidant Sales

Corporation

OF COUNSEL:

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#### **CERTIFICATE OF SERVICE**

I hereby certify that I served a copy of the foregoing on:

Thomas J. Knight HUBBARD & KNIGHT 1125 Noble Street P.O. Box 1850 Anniston, Alabama 36202

Steve R. Morris Morris Law Office P.O. Box 814 Wedowee, Alabama 36278

Counsel for Plaintiff

Michael K. Wright Esq. Starnes & Atchison LLP 100 Brookwood Place, 7th Floor Birmingham, AL 35209 Counsel for Michael Aikens, M.D.

via U.S. Mail this 19th day of July, 2007.

# EXHIBIT A

Document 1-2

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Document 13

Filed 03/16/2006

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JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

NOV - 7 2005

### RELEASED FOR PUBLICATION

FILED CLERK'S OFFICE

#### DOCKET NO. 1708

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE GUIDANT CORP. IMPLANTABLE DEFIBRILLATORS PRODUCTS LIABILITY LITIGATION

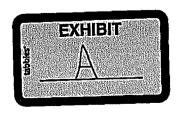
BEFORE WM. TERRELL HODGES, CHAIRMAN, JOHN F. KEENAN, D. LOWELL JENSEN, J. FREDERICK MOTZ, ROBERT L. MILLER, JR., KATHRYN H. VRATIL AND DAVID R. HANSEN, JUDGES OF THE PANEL

#### TRANSFER ORDER

This litigation currently consists of two actions in the District of Minnesota and one action each in the Central District of California, Southern District of Florida, Southern District of Indiana and Eastern District of New York as listed on the attached Schedule A.¹ Before the Panel are two motions, pursuant to 28 U.S.C. § 1407, that taken together seek centralization for coordinated or consolidated pretrial proceedings of the six actions. Plaintiff in one District of Minnesota action and plaintiff in the Southern District of Indiana action both seek centralization in the district in which their respective actions are pending. Defendants Guidant Corp., Guidant Sales Corp., and Cardiac Pacemakers, Inc. (collectively Guidant) initially opposed the motions, but now agree that centralization is warranted; however, the defendants propose the Northern District of Illinois as transferee district. Plaintiffs in all actions before the Panel agree that centralization is appropriate, as do plaintiffs in numerous potential tag-along actions, but some responding plaintiffs suggest transferee districts other than those proposed by the movants and Guidant, including the Northern District of California, Southern District of Pennsylvania, among others.

On the basis of the papers filed and hearing session held, the Panel finds that these six actions involve common questions of fact, and that centralization under Section 1407 in the District of Minnesota will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. These actions share allegations that certain implantable defibrillator devices manufactured by Guidant were defective and caused injury, or the threat of injury, to the plaintiffs and putative class members. Plaintiffs in some potential tag-along actions also bring claims related to pacemakers manufactured by Guidant. All devices at issue in these actions have been the subject of

<sup>.</sup> The Panel has been notified of over 60 potentially related actions pending in multiple federal districts. In light of the Panel's disposition of this docket, these actions will be treated as potential tag-along actions. See Rules 7.4 and 7.5, R.P.J.P.M.L., 199 F.R.D. 425, 435-36 (2001).



Case 3:07-cv-00661-MHT-TFM

Document 1-2

Filed 07/19/2007

Page 3 of 4

Case 3:06-cv-00375-RGJ-KLH 11/07/2005 11:57 FAX 2025024833

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Document 13 JPML.

Filed 03/16/2006

Page 2 of 3

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- 2 -

written warnings, medical advisories, recalls, or some combination thereof. Centralization under Section 1407 is necessary in order to eliminate duplicative discovery; prevent inconsistent pretrial rulings, especially with respect to class certification; and conserve the resources of the parties, their counsel and the judiciary.

Given the varied locations of parties and witnesses in this docket and the geographic dispersal of pending actions, it is clear that a wide array of suitable transferee districts presents itself. In concluding that the District of Minnesota is an appropriate forum for this docket, we observe that this district, where at least ten actions are already pending before one judge, is a geographically central, metropolitan district equipped with the resources that this complex products liability litigation is likely to require. The District of Minnesota also has a nexus to this docket given the location there of key Guidant facilities involved in the development and manufacturing of the relevant devices.

IT IS THEREFORE ORDERED that, pursuant to 28 U.S.C. § 1407, the actions listed on Schedule A and pending outside the District of Minnesota are transferred to the District of Minnesota and, with the consent of that court, assigned to the Honorable Donovan W. Frank for coordinated or consolidated pretrial proceedings with the actions listed on Schedule A and pending in that district.

FOR THE PANEL:

Wm. Terrell Hodges

Chairman

sincethon

Case 3:06-cv-00375-RGJ-KLH 11/07/2005 11:57 FAX 2025024833

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#### SCHEDULE A

#### MDL-1708 - In re Guidant Corp. Implantable Defibrillators Products Liability Litigation

#### Central District of California

Joseph Gabriele v. Guidant Corp., C.A. No. 5:05-487

#### Southern District of Florida

Eugene Clasby v. Guidant Corp., C.A. No. 1:05-21485

#### Southern District of Indiana

John Brennan v. Guidant Corp., et al., C.A. No. 1:05-827

#### District of Minnesota

Edith Walker v. Guidant Corp., C.A. No. 0:05-1141 Darci L. Munson v. Guidant Corp., et al., C.A. No. 0:05-1153

#### **Eastern District of New York**

Larry Wenig, et al. v. Guidant Corp., et al., C.A. No. 2:05-2822

## Exhibit B

SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY
<ul> <li>■ Complete items 1, ∠, and 3. Also complete item 4 if Restricted Delivery is desired.</li> <li>■ Print your name and address on the reverse so that we can return the card to you.</li> <li>■ Attach this card to the back of the mailpiece,</li> </ul>	A. Signature  X
or on the front if space permits.	D, Is delivery address different from item 1?  Yes
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or PO Box No. 4100	Hamline, Auc North INN 55112

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ALABAMA JUDICIAL DATA CENTER RANDOLPH COUNTY

ORDER FOR SERVICE AND RETURN

CV 2007 000085.00

STEVEN RICHARD PERRY

IN THE CIRCUIT RANDOLPH COUNTY

SUE F BRADLEY VS GUIDANT CORPORATION ET ALS

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SUMMONS & COMPLAINT

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TO ANY SHERIFF OR ANY AUTHORIZED AGENT:
YOU ARE HEREBY ORDERED TO DELIVER THE ATTACHED DOCUMENT

TO THE ABOVE NAMED PERSON AT THE ADDRESS INDICATED.

NAME / ADDRESS ABOVE

DATE

SIGNATURE OF SERVER

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PREPARED: 06/20/2007

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#### ALABAMA JUDICIAL DATA CENTER COUNTY RANDOLPH

ORDER FOR SERVICE AND RETURN

CV 2007 000085.00

STEVEN RICHARD PERRY

BY:

IN THE CIRCUIT COURT OF RANDOLPH COUNTY

SUE F BRADLEY VS GUIDANT CORPORATION ET ALS

SERVE ON:

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NOTES:

SUMMONS & COMPLAINT

TO ANY SHERIFF OR ANY AUTHORIZED AGENT:

YOU ARE HEREBY ORDERED TO DELIVER THE ATTACHED DOCUMENT TO THE ABOVE NAMED PERSON AT THE ADDRESS INDICATED.

06/20/2007 DATE

CLERK: CHRIS MAY

P. O. BOX 328 WEDOWEE AL (256)357-4551

36278

SIGNATURE OF SERVER

I HEREBY CERTIFY THAT I PERSONALLY DELIVERED A COPY OF THE ATTACHED COUNTY, ALABAMA DOCUMENT IN TO:

NAME / ADDRESS ABOVE

DATE

OPERATOR: CYW

PREPARED: 06/20/2007

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#### ALABAMA JUDICIAL DATA CENTER RANDOLPH COUNTY

ORDER FOR SERVICE AND RETURN

CV 2007 000085.00

**STEVEN RICHARD PERRY** 

BY: (

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SERVER

IN THE CIRCUIT COURT OF RANDOLPH

COUNTY

SUE F BRADLEY VS GUIDANT CORPORATION ET ALS

SERVE ON: D001

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NOTES:

SUMMONS & COMPLAINT

TO ANY SHERIFF OR ANY AUTHORIZED AGENT:
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06/20/2007 DATE

CLERK: CHRIS MAY

P. O. BOX 328

WEDOWEE AL 36278

(256)357-4551

I HEREBY CERTIFY THAT I PERSONALLY DELIVERED A COPY OF THE ATTACHED DOCUMENT IN \_\_\_\_\_\_\_ COUNTY, ALABAMA \_\_\_\_\_ COUNTY, ALABAMA

Michael Aikers

149 Chesnut St.

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DATE

SIGNATURE OF

OPERATOR: CYW

PREPARED: 06/20/2007

State of Alab Unified Judi			SUMMONS	*	Case Number
Form C-34	Rev 6/88		- CIVIL -		W07-085
IN THE		CIRCUIT	COURT OF	RANDOLF	PH COUNTY
Plaintiff	SUE	F. BRADLEY	v. Defendant G	UIDANT CORF	PORATION, et. als.
NOTICE TO		Dr. Michae	el Aikens, 32 Medical Drive, Roa	anoke, AL 36274	4
TO PROTECT Y	OUR RIGHTS. ' ER ADMITTING L ANSWER MU	YOU OR YOUR ATTO OR DENYING EACH A ST BE MAILED OR HA	IMMONS IS IMPORTANT AND DRNEY ARE REQUIRED TO FI ALLEGATION IN THE COMPLAI AND DELIVERED BY YOU OR Y THOMAS J. KNIGHT	LE THE ORIGIN NT WITH THE C OUR ATTORN	NAL OF YOUR WRITTEN
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RETURN ON		ertified mail recei	ved in this office on		Jerk of Circuit Court
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Date	- 15 <sup>1-1</sup>		Server's Signatu	re	
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	State of Alabama Unified Judicial System  SUMMONS		Case Number				
Form C-34	Rev 6/88		- CIVIL -		CV01-025		
IN THE		CIRCUIT	COURT OF	RANDOLI	PH COUNTY		
Plaintiff	SUE	F. BRADLEY	v. Defendant G	UIDANT CORI	PORATION, et. als.		
NOTICE TO		Linda Garr	mon, 727 County Road 154, Br	emen, AL 35033	3		
TO PROTECT Y	OUR RIGHTS. ER ADMITTING R ANSWER MU	YOU OR YOUR ATTO OR DENYING EACH A	MMONS IS IMPORTANT AND PRNEY ARE REQUIRED TO F LLEGATION IN THE COMPLA ND DELIVERED BY YOU OR THOMAS J. KNIGHT	ILE THE ORIGININT WITH THE C	NAL OF YOUR WRITTEN		
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Case Number State of Alabama **SUMMONS** Unified Judicial System - CIVIL -Form C-34 Rev 6/88 **RANDOLPH** CIRCUIT COUNTY COURT OF \_\_\_\_ IN THE v. Defendant GUIDANT CORPORATION, et. als. **Plaintiff** SUE F. BRADLEY GUIDANT CORPORATION, c/o Sr. Regulatory Affairs Assoc., 4100 Hamline Ave. North, St. Paul, MN 55112 NOTICE TO THE COMPLAINT WHICH IS ATTACHED TO THIS SUMMONS IS IMPORTANT AND YOU MUST TAKE IMMEDIATE ACTION TO PROTECT YOUR RIGHTS. YOU OR YOUR ATTORNEY ARE REQUIRED TO FILE THE ORIGINAL OF YOUR WRITTEN ANSWER, EITHER ADMITTING OR DENYING EACH ALLEGATION IN THE COMPLAINT WITH THE CLERK OF THIS COURT. A COPY OF YOUR ANSWER MUST BE MAILED OR HAND DELIVERED BY YOU OR YOUR ATTORNEY TO THE PLAINTIFF OR THOMAS J. KNIGHT WHOSE PLAINTIFF'S ATTORNEY 1125 Noble Street, P.O. Box 1850, Anniston, Alabama 36202 ADDRESS IS 30 THIS ANSWER MUST BE MAILED OR DELIVERED WITHIN DAYS AFTER THIS SUMMONS AND COMPLAINT WERE DELIVERED TO YOU OR A JUDGMENT BY DEFAULT MAY BE ENTERED AGAINST YOU FOR THE MONEY OR OTHER THINGS DEMANDED IN THE COMPLAINT. TO ANY SHERIFF OR ANY PERSON AUTHORIZED by the Alabama Rules of Civil Procedure: You are hereby commanded to serve this summons and a copy of the complaint in this action upon the defendant. ☐ Service by certified mail of this summons is initiated upon the written request of pursuant to the Alabama Rules of Civil Procedure. Clerk/Redister TOOK O'S NOT Certified Mail is hereby requested. CHRIS MAY Plaintiff's/Attorney's Signature of Circuit Court **RETURN ON SERVICE:** Return receipt of certified mail received in this office on I certify that I personally delivered a copy of the Summons and Complaint to \_\_ County, Alabama on (Date) Date Server's Signature Address of Server Type of Process Server

State of Alabama Unified Judicial System		SUMMONS		Case Number			
Form C-34	Rev 6/88	·	- CIVIL -		CV07-85		
IN THE		CIRCUIT	COURT OF	RANDOL	PH COUNTY		
Plaintiff	SUE	F. BRADLEY	v. Defendant (	BUIDANT COR	PORATION, et. als.		
NOTICE TO	)		awyers Incorporating SVC, Inc.				
TO PROTECT	YOUR RIGHTS. HER ADMITTING JR ANSWER MU	YOU OR YOUR ATTO OR DENYING EACH A IST BE MAILED OR HA	IMMONS IS IMPORTANT AN ORNEY ARE REQUIRED TO I ALLEGATION IN THE COMPLA AND DELIVERED BY YOU OR THOMAS J. KNIGHT	FILE THE ORIGII LINT WITH THE O YOUR ATTORN	NAL OF YOUR WRITTEN CLERK OF THIS COURT. A		
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State of Alabama Unified Judicial System		SUMMONS		Case Number	
Form C-34	Rev 6/88	-	CIVIL -		(LV67-085)
IN THE		CIRCUIT	COURT OF	RANDOL	PH COUNTY
Plaintiff	SUE	F. BRADLEY	v. Defendant	GUIDANT COR	PORATION, et. als.
NOTICE TO		Jeffrey Ha	all, 2323 Avenue F, Ens	sley, AL 35218	
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State of Alabama Unified Judicial System			SUMMONS		Case Number
Form C-34	Rev 6/88		- CIVIL -		CV07-085
IN THE		CIRCUIT	COURT OF	RANDOL	PH COUNTY
Plaintiff	SUE	F. BRADLEY	v. Defendant G	UIDANT COR	PORATION, et. als.
NOTICE TO		Jo	e Napier, 657 Oak Avenue, Pricha	rd, AL 36610	
TO PROTECT '	YOUR RIGHTS. IER ADMITTING R ANSWER MU	YOU OR YOUR A	SUMMONS IS IMPORTANT AND ATTORNEY ARE REQUIRED TO F THALLEGATION IN THE COMPLA HAND DELIVERED BY YOU OR THOMAS J. KNIGHT	ILE THE ORIGINATION OF THE CO	NAL OF YOUR WRITTEN CLERK OF THIS COURT. A
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State of Alabama Unified Judicial System		SUMMONS			Case Number	
Form C-34	Rev 6/88		- CIVIL -		<u> </u>	
IN THE		CIRCUIT	COURT OF	RANDOLI	PH COUNTY	
Plaintiff	SUE	F. BRADLEY	v. Defendant	GUIDANT CORI	PORATION, et. als.	
NOTICE TO		Tab Whisenh	ut, 3418 Countrywood Lane, Biri	mingham, Alabama	35243	
TO PROTECT '	YOUR RIGHTS. IER ADMITTING R ANSWER MU	YOU OR YOUR A OR DENYING EAC	SUMMONS IS IMPORTANT A TTORNEY ARE REQUIRED TO H ALLEGATION IN THE COMPI HAND DELIVERED BY YOU O THOMAS J. KNIGHT	FILE THE ORIGINAL AINT WITH THE C	NAL OF YOUR WRITTEN CLERK OF THIS COURT. A	
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## IN THE CIRCUIT COURT OF RANDOLPH COUNTY, ALABAMA

SUE F. BRADLEY	)
Plaintiff,	) )
vs.	)
GUIDANT CORPORATION,	) CIVIL ACTION CASE NO. <u>CV07-085</u>
GUIDANT SALES CORPORATION,	)
DR. MICHEAL AIKENS,	)
JOE NAPIER, JEFF HALL,	)
TAB WHISENHUT,	)
LINDA GARMON,	
and Sales representatives, and Fictitious	
Defendants A, B, C, D, E, F, being	
those Persons, Sales Representatives,	
Firms or Corporations whose acts,	Filed in Office
omissions, negligence and/or other	
wrongful conduct caused or contributed	)
to the Plaintiff's Injuries	) JUN 2 Ú 2007
and whose true names and Identities	)
are presently unknown to the Plaintiff	) CHRIS MAY
but will be submitted by amendment	Clerk of Circuit Court
when ascertained,	)
	)
Defendants.	)

### **COMPLAINT**

COMES NOW the Plaintiff, Sue F. Bradley and states her claims for relief against Defendants as follows:

Plaintiff, Sue F. Bradley, brings this action against Defendants Guidant Corporation, Guidant Sales Corporation (collectively referred to as "Guidant"), Dr. Micheal Aikens, and Joe Napier, Jeff Hall, Tab Whisenhut, Linda Garmon (collectively sometimes referred to as "Sales Representatives Defendants", included in the "Guidant Defendants") and A, B, C, D, E, and F, whether singular or plural, being those persons, firms or entities who or which proximately caused or contributed to the Plaintiff's personal injuries and the other damages as complained of herein whose true names are unknown to the Plaintiffs but will be added by amendment when correctly ascertained. The Plaintiff was implanted with a Guidant Corporation pacemaker manufactured and sold by the Defendants. Plaintiff brings this action to recover damages for personal injury against Guidant, which designed, manufactured and tested the following: Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, and against all the Defendants ("Defendants"), who sold marketed, implanted, distributed and placed the said products in the stream of commerce.

The Guidant Defendants have engaged in a pattern and practice of deception concerning their implantable cardiac devices. For example, on May 24, 2005, the New York Times reported that for three years Guidant concealed from doctors and others that its Ventak Prism Defibrillators and leads implanted in persons contained a flaw that caused other Ventak Prism Defibrillators to shortcircuit and malfunction. In the same New York Times article, and in a follow-up article published on June 2, 2005, it was also publicly revealed that Guidant changed its manufacturing processes twice in 2002 (April and November) to address this defect but concealed this fact from doctors and the Plaintiff and continued to sell the old defective Defibrillators and leads out of existing inventory. Likewise, Sue F. Bradley was sold and had implanted a defective Guidant cardiac device. The Plaintiff, Sue F. Bradley, was forced to undergo surgery on or about July 8, 2005 due to the Defendants' defective product, misrepresentations and the fraudulent suppression by the Guidantrelated Defendants of the same. Eventually, Defendants recalled the subject devices on or about September 2, 2005, admitting that "Guidant's Cardiac Rhythm Management Quality System has identified two separate failure modes" of the Guidant 1294 which had been surgically removed from Plaintiff. The Plaintiff suffered other damages, injuries, loss, cost and expenses due to the dangerous and defective condition of the said devices, and the misrepresentations concerning the same by

Defendants.

#### **PARTIES**

- 3. Plaintiff, Sue F. Bradley, was at all applicable times, a resident of 422 Peachtree Street, Roanoke, Randolph County, Alabama. On or about September 22, 2004 Plaintiff, Sue F. Bradley, was implanted by Dr. Michael Aikens, A and B with the Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, that had been manufactured by Guidant and sold by Defendants prior to that date. Dr. Aikens provided services and care for Plaintiff at his clinic in Roanoke, Randolph County, Alabama.
- 4. Defendant Guidant acting with the other Defendants, designed, manufactured, tested, marketed, distributed, implanted, promoted, and sold the Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, directly or through wholly owned operating divisions and subsidiaries, including units manufactured prior to September 22, 2004. At all times relevant herein, Guidant was and is a corporation duly formed and existing under and by virtue of the laws of the State of Indiana. Guidant's World Headquarters are located in Indianapolis.
- 5. Defendants Guidant, Hall, Whisenhut, Napier and Garmon called upon the Plaintiff's treating physicians including Dr. Michael Aikens, A and B on multiple occasions prior to September 22, 2004. At these times they presented fraudulent information regarding the safety of Guidant pacemakers, defibrillators and leads and/or other fraudulently suppressed material information regarding the safety of Guidant pacemakers, defibrillators and leads and/or misrepresented defects in the pacemakers and/or placed Guidant pacemakers and defibrillators and leads in the stream of commerce by providing those pacemakers, defibrillators and leads to doctors.

- 6. Events constituting part of, and relevant to the Plaintiff's claims occurred in Randolph County, Alabama. The Plaintiff was even visited by one or more of the Defendants at her residence at 422 Peachtree Street, Roanoke, Randolph County, Alabama.
- 7. Defendants Guidant Corporation and Guidant Sales Corporation are foreign corporations currently engaged in business, directly or by agent in Randolph County, Alabama. They are collectively refereed to as "Guidant" both above and below.
- 8. The sales representatives Defendants Joe Napier, Jeff Hall, Tab Whisenhut and Linda Garmon as well as Dr. Michael Aikens, A and B are upon information and belief resident citizens of the State of Alabama and have conducted business and/or caused tortious injury in Randolph County, Alabama.

### **FACTUAL ALLEGATIONS**

9. Cardiovascular disease is the leading market for the medical device industry because it is the leading cause of death for both men and women in the United States today and claims more lives each year than the next five leading causes of death combined. Thus there is a huge market for applicable medical devices. To participate in the cardiovascular disease market, Guidant develops, manufactures, and markets products that focus on the treatment of cardiac arrhythmias, heart failure and coronary and peripheral disease. One product line consists of implantable pacemaker systems used to detect and treat abnormal heart rhythms that could result in sudden cardiac death, including implantable cardiac resynchronization therapy defibrillators (CRT-D) systems used to treat heart failure. An implanted pacemaker is designed to be inserted under the skin and to pace the heart into a normal rhythm when it might start otherwise to beat or is beating irregularly. Guidant sometimes calls the Pacemaker, model number 1294, by the name "INSIGNIA Entra". In May, 2004, Defendants represented with regard to the subject devices that the

"INSIGNIA Entra lasts up to 50% longer than the DISCOVERY© pacing system (10.2 years)". The Defendants all participated in representing that this pacemaker "improved longevity projections," constituted "Advanced therapy from Guidant," and to physicians, that the INSIGNIA was "shaping your patients' lives today and tomorrow." In May, 2004, Defendants also represented with regard to the subject devices, that there would be "Fewer device replacements".

10. Implanted pacemakers have been among the fastest growing group of medical devices. Guidant has explained their function and purpose in public statements:

"Every pacemaker system has two parts: the pulse generator, which produces the pacing impulses, and the lead or leads, which deliver the impulses to the heart. The same leads also carry signals back from the heart. By "reading" these signals, the pulse generator is able to monitor the heart's activity and respond appropriately. "Guidant pacemakers operate "on demand." That is, a pacemaker will stand by until the natural rate of the upper and/or lower heart falls below a set rate. Only then will it send out pacing impulses to make the heart contract and pump blood. Some of the pacemaker's pacing and monitoring functions can be adjusted - or programmed - by your physician to best meet your particular needs."...

"One other part of the pacemaker system is the monitoring device used by your doctor or nurse. After implant, a pacemaker's functions may need to be adjusted. Your physician can do this using an external computerized device called a programmer. The programmer works noninvasively (from outside the body). The procedure for checking your pacemaker and adjusting settings is painless and does not require surgery."....

"The leads are insulated wires that run from the pulse generator through a vein to the

inside of a heart chamber or chambers. The pacemaker system monitors the heart by reading heart signals sent back to the pulse generator through the leads. This tells the pacemaker each time the heart chambers contract. For most patients, this gives the pacemaker enough information to decide when pacemaker pulses are needed."....

Defendants explained the biological background for this:

"The S-A Node: Your Heart's Natural Pacemaker

The S-A node is a bundle of specialized cells in your right atrium. The S-A node cells are special because they create the electricity that makes your heart beat. The S-A node normally produces 60-100 electrical signals per minute - this is your heart rate, or pulse.

The S-A node is called the "natural pacemaker" of your heart because it controls your heart rate.

The A-V Node: Your Heart's Electrical Bridge

The A-V node is a bundle of specialized cells between your heart's upper and lower chambers (between the atria and ventricles). The A-V node cells are special because they allow electricity to pass through them. Except in rare conditions, no other cells between the atria and ventricles allow this. So, the A-V node is the "electrical bridge" between the atria and ventricles." ...

"Electrical signals created by the S-A node follow a natural electrical pathway through your heart walls. The movement of the electrical signals causes your heart's chambers to contract and relax. When a signal passes through a chamber wall, the chamber contracts. When the signal has moved out of the wall, the chamber relaxes. In a healthy heart, the chambers contract and relax in a coordinated way, or in

rhythm.

"When your heart beats in rhythm at a normal rate, it's called *sinus rhythm*. A problem in your heart's electrical system can disrupt your heart's normal rhythm. Any kind of abnormal rhythm or heart rate is called an *arrhythmia*. It's normal and healthy for your heartbeat to speed up or slow down during the day as your activity level changes. But it's not normal for your heart to beat out of rhythm. When your heart beats out of rhythm, it may not deliver enough blood to your body."

- 11. A normal heartbeat is the result of electrical impulses that originate in the sinoatrial (SA) node in the upper right chamber of the heart, known as the atrium. The impulse causes the atria to contract, causing blood to fill the ventricles. The impulse travels down to the ventricles causing them to contract, forcing blood out of the heart. This cycle repeats itself, resulting in a normal heartbeat.
- 12. Certain heart conditions, including bradycardia, a condition in which a person's heart beats too slowly to provide sufficient oxygen and nutrients to the body, and atrial fibrillation, a condition in which a person's upper heart chambers beat too fast to be efficient and increase the risk of blood clotting, may be treated by implantation of a pacemaker. A pacemaker acts as a monitoring and response devise to these heart conditions. Pacemakers can be used to regulate heart rhythms that are too low and too high. Guidant manufactures several different pacemaker systems with different settings, features, and capabilities. Essentially, they all include a pulse generator, which produces the pacing impulses, and one or two electrical wires extending out of the top, called leads, which deliver the impulses to the heart. The pacemaker is implanted in the upper chest and the leads run to the heart via blood vessels.

- 13. Guidant has described its manufacturing facilities as "exceptional". In Guidant's 2003 Annual Report, it states, "Experienced technicians-supported by continued investment in stateof-the-art automated manufacturing equipment and expansion--have streamlined manufacturing processes to reduce costs, improve quality, increase through-put and shorten the product development and manufacturing and cycle, speeding the delivery of lifesaving therapies to physicians and patients worldwide." Further expounding on "quality," Guidant emphasized in its 2003 Annual Report that it has "an unrelenting focus on quality in everything" it does. Indeed, Guidant proclaims that: "Quality is essential: lives depend on us. We pledge together to build the most reliable products and services. We work every day to drive Quality into everything that is Guidant."
- Guidant also held itself out as an open provider of information to patients and 14. physicians. In its 2003 Annual Report, it stated that "information for patients, physicians and the public is available around the clock through Guidant's dedicated customer and technical service representatives, as well as its comprehensive web site (www.guidant.com)."
- On July 18, 2005, Guidant Corporation issued a press release and communication 15. to physicians releasing important safety information regarding the Guidant Pacemaker manufactured and sold by the company. In that communication to physicians, Guidant advised doctors that a seal within the specified pacemakers may leak, allowing excessive moisture into the device which may affect the electronic circuits.
- According to the July 18, 2005 Guidant letter to physicians, excessive moisture in 16. a pacemaker may cause the device to fail to provide pacing or cause a rapid heart rate or other unexpected behaviors. Such problems may occur without warning and result in loss of consciousness heart failure, and/or death.

- In its July 18, 2005 letter, Guidant notified physicians that it had identified sixty-17. nine pacemaker devices that may have exhibited failure due to internal leakage. Guidant further stated that approximately 18,000 of the Guidant Pacemakers remain in service in the United States.
- Eventually, Defendants admitted on September 2, 2005 that "Guidant's Cardiac 18. Rhythm Management Quality System has identified two separate failure modes" of the Guidant 1294 which had been surgically removed from Plaintiff. Although Defendants admitted to 36 failures in the first mode and 16 failures in the second mode, it did not include the failure of Plaintiff's Guidant 19. 1294 among these, and so the numbers given by Guidant are suspect. Defendants stated in the September 22, 2005 letter that "The United States Food and Drug Administration (FDA) may classify this communication action as a recall." The FDA, of course, did include the Guidant 1294 in the Enforcement Report for November 30, 2005 as recalled, with Guidant Corporation named by the FDA as the recalling firm.
- Defendants, through Joe Napier, had specifically contacted Plaintiff and met with her 20. in Dr. Aiken's office approximately one month after the Guidant 1294 was implanted.
- 21. Defendants, through Joe Napier, had specifically represented to Plaintiff when they met with her in Dr. Aiken's office after the Guidant 1294 was implanted that, "Yours is not the one that was recalled."
- On July 18, 2005, the FDA classified the notification as a Class I recall of the 22. listed Guidant Pacemakers. On September 22, 2005 the 1294 was specified in a "dear doctor" communication.
- In classifying the recall, the FDA signaled the level of threat a patient is exposed 23. to when implanted with a recalled device. The FDA judged the Guidant Pacemakers as having "a reasonable probability that if a particular device is malfunctioning, the malfunctioning device will

cause serious adverse health consequences or death." (Emphasis added).

- On January 1, 2006, Guidant issued a letter addressed to patients in which it stated 24. that it had identified 150 incidents out of 131,500 Guidant Pacemakers. Guidant stated that as a result of the incidents in the Guidant Pacemakers, several patients lost consciousness or developed possible heart failure. Guidant increased its estimate of Guidant Pacemakers still in use in the United States to 22,500.
- When Plaintiff was implanted with a Pacemaker, model number 1294, serial number 25. 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, she was unaware of the design and/or manufacturing defect within her device, of which Defendants knew, or should have known, prior to her implantation surgery.
- 26. Plaintiff had no knowledge that her pacemaker possessed any defect, much less the life-threatening defect described above, until learning of it from the business section of her local newspaper.
- 27. Plaintiff, fully and completely dependant on a pacemaker for cardiac regulation and stabilization, relies on the functioning of a pacemaker at all times.
- 28. Defendants never directly or indirectly informed Plaintiff of the risks associated with the design and/or manufacturing defect in the pacemaker implanted in Plaintiff known to Defendants, or about which they reasonably should have known.
- Defendants knew or should have known about the design and/or manufacturing 29. defects associated with the Guidant Pacemakers implanted in Plaintiff and the Class, and had a duty to inform them about the risks associated with the design and/or manufacturing defects of the devices.

- Plaintiff reasonably relied on Defendants' representations that the Guidant 30. Pacemaker implanted into her contained no design and/or manufacturing defects. Having not been informed about the design and/or manufacturing defects present in Defendants' Guidant Pacemaker, Plaintiff chose to implant the device.
- Unsuspecting of any design and/or manufacturing defect associated with 31. Defendants' Guidant Pacemaker, Plaintiff has been injured as a result of the defect in the device implanted in her.
- It also was discovered in the investigation of this case that in its ENFORCEMENT 32. REPORT for June 11, 2003, the FDA had designated the "Insignia Plus Multiprogrammable Pacemaker, DDR Model

1294" as included in FDA's "Recall # Z-0892-03" know to Guidant since at least May 6, 2003.

- Defendant Joe Napier and defendants C and D, whose names are otherwise unknown to plaintiff, participated in various aspects of the implantation, siting, placement, setting, computer set-up, selection, and other aspects of the Guidant pacemaker and its leads, and also with regard to the replacement thereof. The acts of the defendants included personal visits with the plaintiff for the purpose of dealing with and handling and otherwise reviewing and treating plaintiff with regard to her pacemaker, in Randolph County, Alabama.
- Defendant Joe Napier personally called on plaintiff and said to her that her device was "not recalled" but in fact it has been recalled.
- Plaintiff incorporates by reference all relevant paragraphs hereof as if fully set forth 35. here and further alleges as follows:
- On or about September 22, 2004, plaintiff, was under the medical care and subject to 36. treatment and a procedure by defendants, Dr. Michael Aikens, A and B, at the facilities of the

defendants. At said date and in said place, defendants, Dr. Michael Aikens, A and B, performed a procedure known as a pacemaker insertion upon the person of plaintiff.

- 37. On or about said date, defendants, Dr. Michael Aikens, A and B, did negligently perform medical and related services for and on the person of plaintiff in that the said, Dr. Michael Aikens, A and B, defendants herein, did breach the applicable standard of care in his/her performance of his/her responsibilities in taking and selecting adequate sites in the plaintiff, in taking readings and observations in the course of the said procedure, in examining the colon of plaintiff, in performing the pacemaker procedure, in failing to exercise that level and standard of care expected from a normal and reasonable physician in like circumstances with regard to an inspection for the early detection of, and/or prevention of pacemaker failure, and other pacemaker problems or failure and related issues, and in otherwise performing his duties and functions under the circumstances of his/her care and treatment of plaintiff.
- 38. On or about June 30, 2005, Plaintiff Sue Bradley was experiencing severe chest pain and paroxysmal atrial fibrillation, despite the presence of a Guidant pacemaker. She was put under the care, again, of Dr. Michael Aikens.
- 39. On or about July 8, 2005, plaintiff, was under the medical care and subject to treatment and a procedure by defendants, Dr. Michael Aikens A and B, at the facilities of the defendants. At said date and in said place, defendants, Dr. Michael Aikens, A and B, performed a procedure known as a Generator Change and Lead Revision upon the person of plaintiff.
- 40. On or about said date, defendants, Dr. Michael Aikens, A and B, did negligently perform medical and related services for and on the person of plaintiff in that the said Dr. Michael Aikens, A and B, defendants herein, did replace the existing, recalled Guidant pacemaker with a St. Jude ADX-DR Model #5380.

- 41. On or about July 8 and 9, 2005, defendants, Dr. Michael Aikens, A and B, did negligently perform medical and related services for and on the person of plaintiff in that the said Dr. Michael Aikens, A and B, defendants herein, did perform another invasive procedure on the plaintiff, called an Atrial and Ventricular Lead Replacement. Defendant had failed to remove the old Guidant leads during the previous invasive procedure on the previous day, causing inappropriate sensing and atrial fibrillation. This second invasive procedure caused the plaintiff undue bodily harm.
- 42. On July 8,2005, or thereabouts, Plaintiff Sue Bradley was admitted to the hospital for purposes of removing what Defendant Dr. Michael Aikens referred to as a "malfunctioning device lead recall." He described a procedure performed by him in his Discharge Summary of July 10, 2005 as "permanent pacemaker revision (explantation-implantation of new device)." Dr. Michael Aikens stated in his Discharge Summary of July 10, 2005, that "the patient underwent pacemaker exchange without difficulties and was sent to cardiac special care floor post procedure for recovery. Upon plans to discharge her the following morning it was noted that she was having abnormal pacer spikes id{sic} inappropriate places. Chest x-ray showed that her pacing wires had moved. She went back to the catheterization laboratory for lead revision and subsequently was able to be discharged the following day..."
- 43. On July 8, 2005, Dr. Michael Aikens dictated a further record stating the following with regard to Plaintiff Sue Bradley as to a surgical procedure he performed on that date: "the pacemaker site was subsequently opened. The atrial and ventricular leads were subsequently dissected out. Sensing and testing was performed and found to have optimal atrial sensing and inoptimal ventricle sensing and pacing. Subsequently the ventricle lead was dissected out and the ventricle lead was repositioned and then subsequently found to have optimal sensing and pacing

parameters. The generator was subsequently explanted. A new generator, an identity ADX-DR Model #5380 by St. Jude Medical was subsequently put in .... The device was subsequently attached to the leads and placed in the pacemaker pocket.... again, the device implanted was identity ADX-DR Model #5380 by St. Jude Medical."

- 44. On August 26, 2005, Defendant Dr. Michael Aikens dictated a memorandum of a procedure performed by him entitled "atrial and ventricular lead replacement". He indicated that the "indications" or reasons for this procedure were "high impedance and fracture of a ventricle lead." He describes an additional procedure performed on Plaintiff, Sue Bradley as follows: "... the pacemaker pocket was opened. It was washed with antibiotics. The atrial and ventricular leads were subsequently removed. A new atrial and ventricular lead was subsequently placed, St. Jude Medical 1688 TC, 52 centimeter and 58 centimeter leads. They were attached to the St. Jude 5380 pacemaker. The pacemaker was washed and cleansed with antibiotics. The subcutaneous tissue was subsequently closed with interrupted Chromic....again, the device the patient has is the St. Jude Medical 5380. The new leads were St. Jude Medical 1688 TC. The ones that were removed were Guidant leads." These notes were dictated August 26, 2005, and transcribed and authenticated by Defendant Dr. Michael Aikens on August 27, 2005.
- 45. Defendants, Dr. Michael Aikens, A and B, did otherwise breach the applicable standards of care, and commit acts of actionable negligence with regard to, and in his care and treatment of, plaintiff. Said defendants negligently failed to use reasonable care in selection of an assistant or other personnel, or procedures or directives for examination, implantation, and other investigation of the pacemaker and its associated parts and leads from, and other matters relating to, the plaintiff, with regard to suspected sources of the pacemaker failure of plaintiff, including but not limited to, pacemaker lead failure.

The conduct, acts, and omissions of defendants, Dr. Michael Aikens, A and B, 46. combined and concurred with acts of negligence, wantonness, products liability, breach of duty, and other tort and breach of contract by the other defendants herein, and of others, to proximately cause the pain and suffering experienced by plaintiff, her severe personal injury, sickness, manifesting itself to her beginning on July 8, 2005, to proximately cause, combining and concurring with the other acts and omissions set forth, in the injury and damage of plaintiff.

## PLAINTIFF'S CLAIMS FOR RELIEF

## PRODUCTS LIABILITY UNDER AEMLD AND STRICT LIABILITY PURSUANT TO §402A OF THE RESTATEMENT (SECOND) OF TORTS

- Plaintiff incorporates by reference all other relevant paragraphs into this Count as if 47. fully set forth herein and further alleges as follows:
- 48. Defendants Guidant, designed, manufactured, tested, marketed, distributed, implanted, promoted, and sold the following: Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, and all the Defendants, who designed, manufactured, tested, marketed, distributed, implanted, promoted, and sold the said products in the stream of commerce, and each had an opportunity to inspect the products which were superior to the knowledge or opportunity of the consumer, Plaintiff herein.
- The Defendant Guidant's Pacemaker, model number 1294, serial number 104751, 49. Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, manufactured and sold by Guidant and fictitiously designated defendants products were defective and unreasonably dangerous in design, manufacture and/or fabrication in that, when they left the hands of the Defendants as manufacturers, sellers, designers, testers, marketers, distributors,

promoters, and/or suppliers the foreseeable risks exceeded the benefits associated with the design or fabrication and they were unreasonably dangerous and defective. Plaintiff shows that she suffered injury or damages as a result of the sale by Defendants who sold the product in defective condition unreasonably dangerous to the ultimate consumer, and all the sellers were engaged in the business of selling such product and the product was expected to and did reach the user or consumer without substantial change in condition in which it was sold.

- 50. In addition or alternatively, the Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, manufactured and sold by Guidant, and fictitiously designated defendants and/or supplied by them was defective in manufacture, design or formulation, in that, when it left the hands of the manufacturers, sellers, and/or suppliers, it was unreasonably dangerous, in that it did not meet the reasonable expectations of the ordinary consumer, and was more dangerous than an ordinary consumer would expect and more dangerous than other relevant devices. The plaintiff shows that the product was unreasonably dangerous and defective when it left the defendants' control, that it was substantially unaltered when the plaintiff used it, and that it proximately caused the plaintiff's injuries.
- 51. The Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, manufactured and sold by Defendants was also defective due to inadequate warning or instruction because the manufacturers and suppliers knew or should have known that the products created a risk of harm to consumers and the Defendants failed to adequately warn of said risks.
- 52. The Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, reached

the consumer without substantial change in condition in which it was sold and used as intended by the defendants.

- 53. Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, is not fit for its intended purpose and does not meet reasonable expectations of the ordinary consumer.
- 54. The Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, manufactured and sold by Defendants was defective due to inadequate warning and/or inadequate testing.
- 55. The Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, manufactured and sold by Defendants was also defective due to inadequate marketing and post-marketing warnings or instruction because, after the Defendants knew or should have known of the risk of injury from Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, from use of these devices, they failed to provide adequate warnings to users or consumers of the product and continued to promote the product.
- 56. As a consequence of the above-described producing cause and as a legal result of the dangerous and defective condition of the Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, which designed, manufactured, tested, marketed, distributed, implanted, promoted, and sold by Defendants, and as a direct and legal result of the tort, AEMLD violation, negligence, carelessness, other wrongdoing and actions of Defendants described herein, Plaintiff was injured.

- Defendants are designers, developers, manufacturers, testers, marketers, distributors, 57. implantors, promoters, and sellers of the following: Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186.
- The Guidant Pacemaker, model number 1294, serial number 104751, Lead, model 58. number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, designed, developed, manufactured, tested, marketed, distributed, implanted, promoted, and sold by Defendants were and are unaccompanied by proper warnings regarding all possible adverse side effects associated with the use of Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186 and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of the side effects.
- 59. Defendants failed to perform adequate testing in that adequate testing would have shown that Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, used individually and/or in any combination thereof, possessed serious potential hazards with respect to which full and proper warnings accurately and fully reflecting hazards, symptoms, scope and severity should have been made, both with respect to the use of any of these Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, individually and with respect to any combination use of these devices.
- Defendants also failed to effectively warn users and physicians that numerous other 60. devices made by other manufactures did not break as did the subject device.

- The Guidant Pacemaker, model number 1294, serial number 104751, Lead, model 61. number 4088, serial number 103329, and Lead, model number 4087, serial number 215186. designed, developed, manufactured, tested, marketed, distributed, implanted, promoted, and sold by Defendants were defective due to inadequate post-marketing warning or instruction because, after the manufacturer, developer, designer, and marketer knew or should have known of the risk of injury from the Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, it and they failed to provide adequate warnings to users or consumers of the product and continued to aggressively promote the product, and no accurate or appropriate warning was given to Plaintiff or her physicians by Guidant or the other defendants at the point and time of sale or by anyone else.
- The producing cause and legal result of the dangerous and defective condition of The 62. Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186 as designed, developed, manufactured, tested, marketed, distributed, implanted, promoted, and sold by Defendants, and as a direct and legal result of the negligence, carelessness, other wrongdoing and action(s) of Defendants described herein:
- a. Plaintiff has been injured in health, strength and activity and suffered injuries to body and mind, the exact nature and extent of which are not known at this time;
- b. Plaintiff has sustained economic loss, including loss of earnings and diminution or loss of earning capacity, the exact amount of which is presently unknown;
- c. Plaintiff required reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and

services in an amount as yet unascertained.

# COUNT II MALPRACTICE CLAIM AGAINST PHYSICIAN

63. Plaintiff incorporates by reference the specificity in paragraphs 35 through 46 of this Complaint and all relevant paragraphs hereof as if fully set forth here and further alleges that the Defendants, Dr. Michael Aikens, A and B, did otherwise breach the applicable standards of care, and commit acts of actionable negligence with regard to, and in his care and treatment of, plaintiff. Said defendants negligently failed to use reasonable care in selection of an assistant or other personnel, or procedures or directives for examination, implantation, and other investigation of the pacemaker and its associated parts and leads from, and other matters relating to, the plaintiff, with regard to suspected sources of the pacemaker failure of plaintiff, including but not limited to, pacemaker lead failure. The conduct, acts, and omissions of defendants, Dr. Michael Aikens, A and B, combined and concurred with acts of negligence, wantonness, products liability, breach of duty, and other tort and breach of contract by the other defendants herein, and of others, to proximately cause the pain and suffering experienced by plaintiff, her severe personal injury, sickness, manifesting itself to her beginning on July 8, 2005, to proximately cause, combining and concurring with the other acts and omissions set forth, in the injury and damage of plaintiff.

# COUNT III PRODUCT LIABILITY (PURSUANT TO RESTATEMENT SECOND OF TORTS SECTION 402A)

- 64. Plaintiff incorporates by reference to all other paragraphs as if fully set forth here and further alleges as follows:
- 65. Defendants are manufacturers and/or suppliers of the subject Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and

Lead, model number 4087, serial number 215186.

- The Guidant Pacemaker, model number 1294, serial number 104751, Lead, model 66. number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, manufactured and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.
- Alternatively, the Guidant Pacemaker, model number 1294, serial number 104751, 67. Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, manufactured and/or supplied by Defendants was defective in design or formulation, in that, when they left the hands of the manufacturer and/or suppliers, they were unreasonably dangerous, they were more dangerous than an ordinary consumer would expect and more dangerous than other forms of pacemakers.
- The Guidant Pacemaker, model number 1294, serial number 104751, Lead, model 68. number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, manufactured and/or supplied by Defendants was also defective due to inadequate warning or instruction because the manufacturer knew or should have known that the product created a risk of harm to consumers and the Defendants failed to adequately warn of said risks.
- Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, manufactured and/or supplied by Defendants was defective due to inadequate warning and/or inadequate testing.
- The Guidant Pacemaker, model number 1294, serial number 104751, Lead, model 70. number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, manufactured and/or supplied by Defendants was defective due to inadequate post-marketing

warning or instruction because, after the manufacturer knew or should have known of the risk of injury from Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, they failed to provide adequate warnings to physicians or users or consumers of the product and continued to promote the product.

- With, as the producing cause and legal result of the defective condition of Guidant 71. Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, as manufactured and/or supplied by Defendants, and as a direct and legal result of the negligence, carelessness, other wrongdoing and action(s) of Defendants described herein:
- a. Plaintiff has been injured in health, strength and activity and suffered injuries to body and mind, the exact nature and extent of which are not known at this time;
- b. Plaintiff has sustained economic loss, including loss of earnings and diminution or loss of earning capacity, the exact amount of which is presently unknown;
- c. Plaintiff required reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

## COUNT IV

- Plaintiff incorporates by reference all other paragraphs as if fully set forth here and 72. further alleges as follows:
  - Defendants Guidant and fictitious defendants had a duty to exercise reasonable care 73.

in the manufacture, sale and/or distribution of Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186 into the stream of commerce, including a duty to assure that the products did not cause users to suffer from injuries unreasonable, dangerous side effects. Said Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, into interstate commerce in that said Defendants knew or should have known that the products, the Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, created a high risk of unreasonable dangers and dangerous side effects, some of which can be fatal or crippling.

- 74. Said Defendants were negligent in the design, development, manufacturing, testing, marketing, distributing, implanting, promoting, and sale of Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, in that they:
- a. Failed to use due care in designing and manufacturing Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, so as to avoid the aforementioned risks to individuals when Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, were being used for implantation;
- b. Failed to accompany their products with proper warnings regarding all possible adverse side effects associated with the use of Guidant Pacemaker, model number 1294, serial number

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104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of the side effects;

- c. Failed to conduct adequate pre-clinical and clinical testing and post-marking surveillance to determine the safety of Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186;
- d. Failed to provide adequate training to medical care providers for appropriate use of Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186,;
- e. Failed to warn physicians or Plaintiff, prior to actively encouraging the sale of Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, either directly or indirectly, orally or in writing, about the following: (1) about the need for comprehensive, regular medical monitoring to ensure early discovery of potentially fatal breakage; (2) the danger of breakage; (3) the dangers of the consequences of breakage; (4) proper installation of the devices;
- f. Failed to warn Plaintiff, physicians and general public of aforesaid side effects, which can cause serious health risks;
- g. Failed to warn that the costs associated with Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, could exceed other comparable forms of implantation, particularly for those who were like plaintiff; and
  - h. Were otherwise careless or negligent.

- Despite the fact that said Defendants knew or should have known that Guidant 75. Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, caused unreasonable, dangerous breakage which many users would be impotent to remedy by any means, said Defendants continued to market Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, including to Plaintiff's health care providers, when there were safer alternative methods of infusion available.
- Said Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of said Defendants' failure to exercise ordinary care as described above.
- Said Defendants' negligence was a proximate cause of Plaintiff's injuries, harm and 77. economic loss which she suffered and will continue to suffer as previously described. Plaintiff requires reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

## **BREACH OF EXPRESS WARRANTY**

- Plaintiff incorporates by reference all other paragraphs as if fully set forth here and 78. further alleges as follows:
- Defendants Guidant and fictitious defendants expressly warranted that Guidant 79. Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, were safe and well accepted by

patients studied, and free from a danger of breakage.

- The subject Guidant Pacemaker, model number 1294, serial number 104751, Lead, 80. model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, does not conform to these express representations because it is not safe and has high levels of serious dangers, including life threatening side effects of breakage, and did in fact break.
- As a direct and proximate result of the breach of said warranties, Plaintiff suffered and will continue to suffer injury, harm and economic loss as alleged herein. Plaintiff requires reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

# BREACH OF IMPLIED WARRANTY

- Plaintiff incorporates by reference all other paragraphs as if fully set forth here and 82. further alleges as follows:
- 83. At the time Defendants marketed, sold, and distributed the Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, for use by Plaintiff, Defendants knew of the use for which the Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, were intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.
- Plaintiff received the implied warranty from Defendants and Plaintiff had no skill and no basis on which to form an independent judgment as to the product of Defendants as to whether the Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088,

serial number 103329, and Lead, model number 4087, serial number 215186, were of merchantable quality, safe and fit for their intended use.

- 85. Contrary to such implied warranty the Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, were not of merchantable quality, safe or fit for their intended use, because the products were and are unreasonably dangerous and unfit for the ordinary purpose for which they were used as described above. Defendants otherwise breached the implied warranty.
- As a direct and proximate result of the breach of implied warranty, Plaintiff suffered 86. and will continue to suffer injury, harm and economic loss as alleged herein. Plaintiff requires reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

# MISREPRESENTATION, FRAUD, SUPPRESSION AND DECEIT

- Plaintiff incorporates by reference all other paragraphs as if fully set forth here and 87. further alleges as follows:
- Plaintiff alleges on information and belief that even if misrepresentations made by 88. Defendants, Guidant and Sales Representatives Defendants, and fictitious defendants, were innocent misrepresentations they are nonetheless actionable under Alabama and other law. Defendants have made and some of them continue to make false and fraudulent misrepresentations to Plaintiff, physicians and general public including, but not limited to, that the Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead,

model number 4087, serial number 215186, are safe, fit and effective for their uses and their components are not hazardous to the health of users.

- 89. At all pertinent times, Defendants conducted, and/or conspired jointly to conduct, a sales and marketing campaign to promote the sale of Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, through advertisements and other promotional literature and fraudulently deceived the Plaintiff, physicians and the general public as to the health risks and consequences of Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186. Defendants also failed to disclose other effective methods for pacing. Defendants suppressed material facts that, if disclosed to Plaintiff would have resulted in Plaintiff's refusal of Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186.
- 90. Defendants Guidant, Sales Representatives Defendants and fictitiously designated defendants' misrepresentation and suppressions of material facts were done intentionally, willfully and/or negligently. Plaintiff and her physician reasonably relied upon the skill and judgment of said Defendants as to whether the Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186, were of merchantable quality, safe and fit for their intended uses.
- 91. In reliance of the foregoing misrepresentation whether innocent, negligent or not by Defendants, Plaintiff was induced to and did subject herself to the use of Guidant Pacemaker, model number 1294, serial number 104751, Lead, model number 4088, serial number 103329, and Lead, model number 4087, serial number 215186. If the Plaintiff had known the true facts, she would not

have taken such action and subjected herself to the aforesaid risks.

As a result of Defendants' negligence, false and fraudulent misrepresentation, 92. fraudulent suppression and concealment, and conspiracy, Plaintiff has suffered harm, injuries and damages as described above. Plaintiff requires reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

## **COUNT VIII** CIVIL CONSPIRACY

- Plaintiff incorporates by reference all other paragraphs as if fully set forth here and 93. further alleges as follows:
- Defendants combined and conspired to do those acts complained of in Count One 94. through Count Eight, as a result of which the Plaintiff has suffered harm, damages and injuries as previously described. Plaintiff requires reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges she may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

WHEREFORE, Plaintiffs demand judgment against Defendants Guidant Corporation, Guidant Sales Corporation (collectively referred to as "Guidant"), Dr. Michael Aikens, Joe Napier, Jeff Hall, Tab Whisenhut, Linda Garmon and A, B, C, D, E, and F, whose true names are unknown to the Plaintiffs but will be added by amendment when correctly ascertained, jointly and severally in such sums of compensatory and punitive damages as the jury determines to be fair, just, and lawful plus costs of Court.

Thomas J. Knight (KNI009) Attorney for Plaintiff

HUBBARD & KNIGHT

1125 Noble Street

Post Office Box 1850

Anniston, Alabama 36202

(256) 237-9586

Steve R. Morris

Attorney for Plaintiff

Morris Law Office

Post Office Box 814

Wedowee, Alabama 36278

(256) 357-9**2**11

State of Alabama Unified Judicial System	COVER SHEET		Case Number	0085				
	CIRCUIT COURT - CIVIL CASE		Date of Filing:	Judge Code:				
Form ARCiv-93 Rev.5/9	9 (Not For Domestic	Relations Cases)	<b>0</b> 6 <u></u> <u> </u>	Year				
	GENERAL INFORMATION							
IN THE CIRCUIT COUR	T OF	RANDOLPH (	COUNTY of County)	, ALABAMA				
SU	JE F. BRADLEY	vv.	GUIDANT CORP	ORATION, et. als.				
	Plaintiff siness	First Defenda	nt Business Government	☐ Individual ☐ Other				
NATURE OF SUIT: Se	lect primary cause of action,			cterizes your action:				
TORTS: PERSONAL INJU  WDEA - Wrongful TONG - Negligen TOWA - Wantonn TOPL - Product TOMM - Malpracti TOLM - Malpracti TOOM - Malpracti TOOM - Malpracti TOXX - Other: TORTS: PERSONAL INJU TOPE - Persona TORE - Real Pro OTHER CIVIL FILINGS ABAN - Abando ACCT - Account APAA - Administ ADPA - Administ	Death ce: General nce: Motor Vehicle ess Liability/AEMLD ce-Medical ce-Legal ice-Other ad Faith/Misrepresentation  RY Il Property	OTHER CIVIL FILINGS  MSXX - Birth/ Enfor  CVRT - Civil F  COND - Conte  CONT - Contr  TOCN - Conv  EQND - Equit  Ele  CVUD - Evicti  FORJ - Forei  FORF - Fruit  MSHC - Habe  PFAB - Prote  RPRO - Real  WTEG - Will/T  COMP - Works						
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HAS JURY TRIAL BEEN DEMANDED? YES NO Note: Checking "Yes" does not constitute a demand for a jury trial. (See Rules 38 and 39, Ala.R.Civ.P, for procedure)								
RELIEF REQUESTED: MONETARY AWARD REQUESTED NO MONETARY AWARD REQUESTED								
ATTORNEY CODE:    K   N   I   0   0   9   Date   Date   Signature of Attorney/Party filing this form								
MEDIATION REQUESTED: ☐ YES ☐ NO ☑ UNDECIDED								

IN THE CIRCUIT COURT OF RANDOLPH COUNTY, ALABAMA

SUE F. BRADLEY,	) 
Plaintiff,	
vs.	CIVIL ACTION NO. CV-07-085
MICHAEL AIKENS, M.D. et al.,	
Defendants.	) ) )

#### **MOTION TO DISMISS**

COMES NOW the defendant, Michael Aikens, M.D., and moves this Court to dismiss the complaint heretofore filed in this matter on the following grounds:

- 1. That the same fails to state a claim upon which relief can be granted.
- 2. This defendant reserves the right to contest venue.

#### MOVANT WAIVES ORAL ARGUMENT.

Respectfully submitted,

/s/Michael K. Wright
Michael K. Wright
WRI005
Attorney for Michael Aikens, M.D.
Starnes & Atchison LLP
100 Brookwood Place, 7<sup>th</sup> Floor
Birmingham, AL 35209
Telephone: (205) 868-6000

Fax: (205) 868-6099

E-mail: MWright@starneslaw.com

#### **CERTIFICATE OF SERVICE**

I hereby certify that on 18 July, 2007, I electronically filed the foregoing with the Clerk of the Court using the Alafile system, which will send electronic notification of such filing to the following:

Thomas J. Knight, Esq. Hubbard & Knight 1125 Noble Street P.O. Box 1850 Anniston, AL 36202

and I hereby certify that I have mailed by United States Postal Service the document to the following non-Alafile participants:

Steve R. Morris, Esq. Morris Law Office P.O. Box 814 Wedowee, AL 36278

Ms. Linda Garmon 727 Co. Rd. 254 Breman, AL 35033

Guidant Corporation c/o Sr. Regulatory Affairs 4100 Hamline Avenue North St. Paul, MN 55112

Guidant Sales Corp. c/o CSC Lawyers Incorporated SV 150 S. Perry Street Montgomery, AL 36104

Mr. Jeffrey Hall 2323 Avenue F Crestline, AL 35218

Mr. Joe Napier 657 Oak Avenue Prichard, AL 36610 Mr. Tab Whisenhut 3418 Countrywood Lane Cahaba Heights, AL 35243

/s/Michael K. Wright
Michael K. Wright
WRI005
Attorney for Michael Aikens, M.D.
Starnes & Atchison LLP
100 Brookwood Place, 7<sup>th</sup> Floor
Birmingham, AL 35209
Telephone: (205) 868-6000
Fax: (205) 868-6099

### EXHIBIT C

#### IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF ALABAMA EASTERN DIVISION

**SUE F. BRADLEY**,

Plaintiff,

VS.

**GUIDANT CORPORATION, GUIDANT SALES** CORPORATION, DR. MICHAEL AIKENS, JOE NAPIER, JEFF HALL, TAB WHISENHUT, LINDA GARMON, et al.,

Defendants.

#### CIVIL ACTION NO.

(removed from the Circuit Court of Randolph County, Alabama, CV-07-85)

#### **DECLARATION OF JEFF HALL**

- I, Jeff Hall, declare as follows:
- I am over twenty-one years of age, am of sound mind, and am 1. competent to make this Declaration. This Declaration is based upon my personal knowledge.
- I was employed for Guidant Sales Corporation, 111 Monument 2. Circle, 29th Floor, Indianapolis, Indiana 46204-5129 for nearly fourteen (14) years. My employment ended in January 17 2005.
- I am not a physician and, accordingly, never prescribed or 3. implanted an Insignia Entra Pacemaker. The physicians with whom I interacted in my job were highly-skilled professionals. These physicians were responsible for

determining whether, in their best medical judgment, a particular patient would benefit from device therapy. Further, physicians chose which device would best suit an individual patient.

- 4. The information that I used during the course of my employment was provided to me by the manufacturer of the Insignia Entra Pacemaker, Cardiac Pacemakers, Inc. ("CPI"). I never had responsibility for the content of any written warnings accompanying the Insignia Entra Pacemaker.
- 5. At no time did I have any involvement in the design, manufacture, development or testing of the Insignia Entra Pacemaker.
- 6. At no time did I ever provide the Insignia Entra Model 1294 Pacemaker, Serial Number 104751, Lead, Model Number 4088, serial number 103329, and lead, model number 4087, serial number 215186, or leads directly to Sue Bradley.
- 7. I did not call on Dr. Michael Aikens, and Opelika, Alabama, where his office is located was not in my territory during my employment with Guidant Sales Corporation.
- 8. At no time did I make any knowing misrepresentation about the safety or efficacy of the Insignia Entra Pacemaker to Sue Bradley, or Ms. Bradley's physician. I acted in good faith and within the scope of my employment

Filed 07/19/2007

at all times in my dealings with physicians who may have prescribed or implanted the Insignia Entra Pacemaker.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 12, 2007.

3

# **EXHIBIT**

#### IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF ALABAMA EASTERN DIVISION

SUE F. BRADLEY,

Plaintiff,

VS.

GUIDANT CORPORATION, GUIDANT SALES CORPORATION, DR. MICHAEL AIKENS, JOE NAPIER, JEFF HALL, TAB WHISENHUT, LINDA GARMON, et al.

Defendants.

#### CIVIL ACTION NO.

(removed from the Circuit Court of Randolph County, Alabama, CV-07-85)

#### **DECLARATION OF JOE NAPPIER**

- I, Joe Nappier, declare as follows:
- 1. I am over twenty-one years of age, am of sound mind, and am competent to make this Declaration. This Declaration is based upon my personal knowledge.
- 2. I was employed for Guidant Sales Corporation, 111 Monument Circle, 29th Floor, Indianapolis, Indiana 46204-5129 for approximately 2 years, until April 30, 2005.
- 3. I am not a physician and, accordingly, never prescribed or implanted an Insignia Entra Pacemaker. The physicians with whom I interacted in

my job were highly-skilled professionals. These physicians were responsible for determining whether, in their best medical judgment, a particular patient would benefit from device therapy. Further, physicians chose which device would best suit an individual patient.

- 4. The information that I used during the course of my employment was provided to me by the manufacturer of the Insignia Entra Pacemaker, Cardiac Pacemakers, Inc. ("CPI"). I never had responsibility for the content of any written warnings accompanying the Insignia Entra Pacemaker.
- 5. At no time did I have any involvement in the design, manufacture, development or testing of the Insignia Entra Pacemaker.
- 6. At no time did I ever provide the Insignia Entra Model 1294 Pacemaker, Serial Number 104751, Lead, Model Number 4088, serial number 103329, and lead, model number 4087, serial number 215186, or leads directly to Sue Bradley.
- 7. I never met or interacted with Sue Bradley prior to or during the implantation of her pacemaker.
- 8. At no time did I make any knowing misrepresentation about the safety or efficacy of the Insignia Entra Pacemaker to Sue Bradley, or Ms. Bradley's physician. I acted in good faith and within the scope of my employment

at all times in my dealings with physicians who may have prescribed or implanted the Insignia Entra Pacemaker.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 14, 2007.

JOE NAPPIER

## EXHIBIT E

#### IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF ALABAMA EASTERN DIVISION

SUE F. BRADLEY,

Plaintiff,

VS.

GUIDANT CORPORATION, GUIDANT SALES CORPORATION, DR. MICHAEL AIKENS, JOE NAPIER, JEFF HALL, TAB WHISENHUT, LINDA GARMON. et al.,

Defendants.

#### **CIVIL ACTION NO.**

(removed from the Circuit Court of Randolph County, Alabama, CV-07-85)

Page 2 of 4

#### **DECLARATION OF TAB WHISENHUNT**

- I, Tab Whisenhunt, declare as follows:
- 1. I am over twenty-one years of age, am of sound mind, and am competent to make this Declaration. This Declaration is based upon my personal knowledge.
- 2. I was employed for Guidant Sales Corporation, 111 Monument Circle, 29th Floor, Indianapolis, Indiana 46204-5129 for approximately six years (6) years, until June 30, 2006.
- 3. I am not a physician and, accordingly, never prescribed or implanted an Insignia Entra Pacemaker. The physicians with whom I interacted in

my job were highly-skilled professionals. These physicians were responsible for determining whether, in their best medical judgment, a particular patient would benefit from device therapy. Further, physicians chose which device would best suit an individual patient.

- 4. The information that I used during the course of my employment was provided to me by the manufacturer of the Insignia Entra Pacemaker, Cardiac Pacemakers, Inc. ("CPI"). I never had responsibility for the content of any written warnings accompanying the Insignia Entra Pacemaker.
- 5. At no time did I have any involvement in the design, manufacture, development or testing of the Insignia Entra Pacemaker.
- 6. At no time did I ever provide the Insignia Entra Model 1294 Pacemaker, Serial Number 104751, Lead, Model Number 4088, serial number 103329, and lead, model number 4087, serial number 215186, or leads directly to Sue Bradley.
- 7. I did not call on Dr. Michael Aikens, and Opelika, Alabama, where his office is located was not in my territory during my employment with Guidant Sales Corporation.
- 8. At no time did I make any knowing misrepresentation about the safety or efficacy of the Insignia Entra Pacemaker to Sue Bradley, or Ms. Bradley's physician. I acted in good faith and within the scope of my employment

at all times in my dealings with physicians who may have prescribed or implanted the Insignia Entra Pacemaker.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 16, 2007.

### **EXHIBIT**

F

#### IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF ALABAMA EASTERN DIVISION

SUE F. BRADLEY,

Plaintiff,

VS.

**GUIDANT CORPORATION, GUIDANT SALES** CORPORATION, DR. MICHAEL AIKENS, JOE NAPIER, JEFF HALL, TAB WHISENHUT, LINDA GARMON, et al.,

(removed from the Circuit Court of Randolph County, Alabama, CV-07-85)

Defendants.

#### **DECLARATION OF LINDA GARMON**

- I, Linda Garmon, declare as follows:
- I am over twenty-one years of age, am of sound mind, and am 1. competent to make this Declaration. This Declaration is based upon my personal knowledge.
- 2. I am currently employed by Guidant Sales Corporation, 111 Monument Circle, 29th Floor, Indianapolis, Indiana 46204-5129.
- 3. I am not a physician and, accordingly, never prescribed or implanted an Insignia Entra Pacemaker. The physicians with whom I interacted in my job were highly-skilled professionals. These physicians were responsible for

determining whether, in their best medical judgment, a particular patient would benefit from device therapy. Further, physicians chose which device would best suit an individual patient.

- 4. The information that I used during the course of my employment was provided to me by the manufacturer of the Insignia Entra Pacemaker, Cardiac Pacemakers, Inc. ("CPI"). I never had responsibility for the content of any written warnings accompanying the Insignia Entra Pacemaker.
- 5. At no time did I have any involvement in the design, manufacture, development or testing of the Insignia Entra Pacemaker.
- 6. At no time did I ever provide the Insignia Entra Model 1294 Pacemaker, Serial Number 104751, Lead, Model Number 4088, serial number 103329, and lead, model number 4087, serial number 215186, or leads directly to Sue Bradley.
- 7. I have not called on Dr. Michael Aikens, and Opelika, Alabama, where his office is located, is not in my territory.
- 8. At no time did I make any knowing misrepresentation about the safety or efficacy of the Insignia Entra Pacemaker to Sue Bradley, or Ms. Bradley's physician. I acted in good faith and within the scope of my employment at all times in my dealings with physicians who may have prescribed or implanted the Insignia Entra Pacemaker.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 16, 2007.

### EXHIBIT G

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

In re:

MASTER FILE

REZULIN PRODUCTS LIABILITY LITIGATION (MDL No. 1348)

00 Civ. 2843 (LAK)

This Document Relates to: 02 Civ. 3583

PRETRIAL ORDER NO. 122 (Motion to Remand in Martin)

LEWIS A. KAPLAN, District Judge.

Plaintiff has moved to remand this action based on his contention that the presence of a nondiverse defendant — plaintiff's treating physician, Garth C. Denyer, M.D. — defeats complete diversity. Defendants object to the Report and Recommendation of Magistrate Judge Katz, which recommended that plaintiff's motion to remand be granted because "defendants have failed to demonstrate that there is no reasonable possibility that plaintiff's negligence claim against the non-diverse physician would be successful." Report & Recommendation at 6. Defendants argue that Dr. Denyer was joined fraudulently, or, alternatively, that he was misjoined with the Manufacturing Defendants.

Plaintiff asserts three theories of negligence against the physician. First, plaintiff asserts that the defendant-physician negligently failed to warn him of the risks linked to Rezulin. Petition ¶ IV(7). As this Court recently found in PTO No. 121, in light of plaintiff's myriad allegations that the defendants withheld information concerning the risks of Rezulin from physicians and others, an entirely conclusory allegation that the physician failed to warn of risks of Rezulin is insufficient to provide the defendant sufficient notice of the claim against him.

See, e.g., Petition ¶ IV(4) ("Defendants failed to provide adequate warnings of dangers and instruction for safe use of the drug."); Petition ¶ VI(2)(f) ("The Pharmaceutical Defendants failed to timely and adequately warn the medical community and/or Plaintiff regarding the risks associated with Rezulin as they became known."); Petition ¶ X(1)(c) ("The Pharmaceutical Defendants were grossly negligent in failing to timely and adequately warn consumers of the known adverse effects of Rezulin...").

PTO No. 121 at n.11 (citing Rodriguez v. Beechmont Bus Svce., Inc., 173 F. Supp.2d 139, 145 (S.D.N.Y. 2001) ("Allegations that are so conclusory that they fail to give notice of the basic events and circumstances of which the plaintiff complains are insufficient as a matter of law."); Strickland v. Brown Morris Pharmacy Inc., Civ. A. No. 96-815, 1996 WL 537736,

Plaintiff next alleges that the physician negligently "fail[ed] to test and monitor her [sic] liver functions." Petition ¶ IV(7). Once again, in light of plaintiff's other allegations that the defendants failed to timely warn of the need for liver function and other body system monitoring,<sup>3</sup> plaintiff's conclusory allegation is insufficient. Plaintiff has failed to allege any basis for supposing that his physician should have conducted liver testing or even what information concerning the need for testing was available to medical professionals at the relevant time.<sup>4</sup>

Plaintiff's third claim of negligence against the physician likewise fails because it does not state on what basis the physician should have known the patient was unable to tolerate Rezulin.

Accordingly, there is no possibility, based on the pleadings, that plaintiff will establish his medical malpractice claim against the nondiverse physician.

at \*2 (E.D. La. Sept. 20, 1996) (conclusory allegations that defendant knew or should have known that drug was dangerous do not warrant remand)).

See, e.g., Petition  $\P X(1)(c)$  ("The Pharmaceutical Defendants were grossly negligent in failing to timely and adequately warn consumers of the known adverse effects of Rezulin, the need for liver function and other body system monitoring."); Petition  $\P IV(4)$  ("Defendants failed to provide adequate warnings of danger and instruction for safe use of the drug."); Petition  $\P VI(2)(c)(ii)$  ("The Pharmaceutical Defendants failed . . . to give adequate warnings regarding the dangers associated with the use of Rezulin and adequate instructions to avoid such dangers.").

This Court need not consider the "Dear Health Care Professional" letters, FDA Talk Paper, letter from Glaxo Wellcome to the President of Sankyo Company Limited, and Rezulin product labels plaintiff appended to his motion to remand. See Motion Exs. C-H. As this Court previously has noted, the propriety of joinder "is to be determined based on the pleadings." In re Rezulin Prods. Liab. Litig., 133 F. Supp.2d 272, 284 (S.D.N.Y. 2001) ("Rezulin I") (internal quotation marks and citation omitted). Moreover, this Court has observed that "[flederal courts across the nation have relied upon that standard to deny remand based on inadequate pleadings and to disregard allegations not contained in the original complaint." Id. (citing cases).

The plaintiff's motion to remand is denied.

SO ORDERED.

Dated: January 6, 2003

Lewis A. Kaplan United States District Judge 3

### EXHIBIT H

2005 Jun-30 AM 10:39 U.S. DISTRICT COURT

N.D. OF ALABAMA

#### IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA SOUTHERN DIVISION

JUANELL Y. McBRAYER WILKES, et al.,	)
Plaintiffs,	)
ν.	) CIVIL ACTION NO. 05-RRA-1214-S
MERCK & CO., INC., et al.,	)
Defendants.	)

#### **ORDER**

(Re Defendants' Motion to Stay, ct. doc. 5; Plaintiff's Motion to Remand, ct. doc. 7)

The complaint and the parties' submissions concerning the above-stated motions have been studied. The plaintiffs allege that the treating resident physicians knew sufficient information about Vioxx and Celebrex to appreciate that neither should have been prescribed to the plaintiffs. They also contradictorily allege that Merck concealed material information from the physician defendants, who would have acted differently if properly warned regarding the risk and dangers associated with Vioxx and Celebrex. Moreover, the plaintiffs' only allegation against the physicians is the conclusory allegation that they "negligently, wantonly, and/or wrongfully prescribed and/or provided samples of the brand-name prescription drugs Vioxx and Celebrex to the plaintiffs with actual and/or constructive knowledge of the risk and dangers associated with the use of Vioxx and Celebrex." Complaint ¶ 63. Under Alabama law,

In any action for injury, damages, or wrongful death, whether in contract or in tort, against a health care provider for breach of the standard of care the plaintiff shall include in the complaint a detailed specification and a factual description of each act and omission alleged by plaintiff to render the health

care provider liable to plaintiff and shall include when feasible and ascertainable the date, time, and place of the act or acts. . . . any complaint which fails to include such detailed specification and factual description of each act and omission shall be subject to dismissal for failure to state a claim upon which relief may be granted.

Ala. Code § 6-5-551. It is noted that numerous cases against Merck have been filed in this court and have been transferred to the MDL court.

Because of the contradictory allegations against the physician defendants, and the failure of the complaint to comply with Alabama law concerning specificity in making allegations against physicians, it appears to be a good possibility that it will be determined that the individual defendants were fraudulently joined. If it were clear that these physicians were not fraudulently joined, and if judges from this district were ruling on the motions to remand, this motion to stay might be denied and the motion to remand ruled on. The opposite being the event, and in order to have consistent rulings, the motion to stay is GRANTED, and all proceedings in this case, including the motion to remand, are STAYED pending action by the MDL court.

DONE this 30th day of June, 2005.

ROBERT R. ARMSTRONG, JR.

UNITED STATES MAGISTRATE JUDGE

## EXHIBIT I

Case 0:07-cv-01129-DWF-AJB

Document 20

Filed 06/04/2007

Page 1 of 15

#### UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

In re: GUIDANT CORP. IMPLANTABLE DEFIBRILLATORS PRODUCTS LIABILITY LITIGATION

MDL No. 05-1708 (DWF/AJB)

This Document Relates to:

Donald Alexander,

v.

Plaintiff,

Civil No. 07-1129 (DWF/AJB)

Boston Scientific Corporation, Guidant Subsidiary of Boston Scientific Corporation, and St. Anthony's Medical Center,

Defendants.

MEMORANDUM OPINION AND ORDER

Donald Alexander, 31057 Oak Ridge Drive, Rocky Mount, MO 65072, pro se.

Timothy A. Pratt, Esq., Deborah A. Moeller, Esq., and Julie R. Somora, Esq., Shook Hardy & Bacon, LLP, counsel for Defendants Boston Scientific Corporation and Guidant Subsidiary of Boston Scientific Corporation.

Douglas Ponder, Esq., Karen C. Moske, Esq., and V. Scott Williams, Esq., Hazelwood & Weber, LLC, counsel for Defendant St. Anthony's Medical Center.

The above-entitled matter is before the Court pursuant to Plaintiff Donald
Alexander's Motion for Remand to St. Louis County Circuit Court and Defendant
St. Anthony's Medical Center's ("St. Anthony's") Motion to Dismiss. For the reasons
stated below, the Court grants Alexander's Motion for Remand as to Defendant

St. Anthony's, but denies the motion as to all remaining Defendants. The Court denies St. Anthony's Motion to Dismiss as moot.

#### **BACKGROUND**

On May 25, 2006, Alexander was implanted with a Model 1291 Guidant pacemaker at St. Anthony's facilities. Alexander alleges that some of St. Anthony's nurses and staff assisted in the implant. Alexander also alleges that St. Anthony's paid for the pacemaker and included the charges for the pacemaker in Alexander's patient billing.

The Model 1291 device that was implanted in Alexander was manufactured in December 2005. Prior to its manufacture, on September 22, 2005, Guidant issued a recall regarding its Model 1291 Guidant pacemakers, among others. The recall was based on two failure modes.

As to the first failure mode, Guidant recommended that physicians "consider the projected low and declining failure rate in addition to the unique needs of individual patients in their medical decisions regarding patient management" and recommended "normal monitoring, as per device labeling." (Aff. of V. Scott Williams in Supp. of Def. St. Anthony's Mot. to Dismiss and Mem. of Law in Opp'n to Pl.'s Mot. for Remand ("Williams Aff.") at Ex. C.) In addition, Guidant stated, "As always, advise patients to seek attention immediately if they experience syncope or lightheadedness." (*Id.*) As to the second failure mode, Guidant recommended the following:

Guidant recommends verifying pacemaker operation in the packaging prior to the implant procedure. Devices exhibiting intermittent or permanent loss or output or telemetry should not be implanted.

Physicians should consider both the very low occurrence rate and that no failures have been observed after successful confirmation of pacing at implant, in addition to the unique needs of individual patients, in their medical decisions regarding patient management.

(Williams Aff. at Ex. C.)

Approximately two months later, on December 12, 2005, Guidant issued an "Advisory Update" that addressed the September 22, 2005 recall letter. There, Guidant explained the following:

In March of 2004, Guidant discontinued shipping from manufacturing facilities INSIGNIA and NEXUS devices susceptible to "Failure Mode 1."

Guidant has recently discontinued shipping from manufacturing facilities INSIGNIA and NEXUS devices susceptible to "Failure Mode 2." While Guidant recommends normal monitoring for patients implanted with these devices, Guidant representatives will retrieve and replace remaining hospital inventory with product free from susceptibility to "Mode 2" perimplant failure.

INSIGNIA and NEXUS devices currently being distributed by Guidant are not subject to either failure mode and therefore are not included in either recall.

(Williams Aff. at Ex. D.) Although Alexander's Model 1291 device was manufactured in December 2005, it is unclear whether the device was manufactured and shipped prior to this December 12, 2005 Advisory Update.

Approximately one month after Alexander's implant surgery, on June 23, 2006, Guidant issued a separate recall of the Model 1291. Thereafter, on July 7, 2006, Alexander received notice from the St. Louis Metro Heart Group that the specific Guidant pacemaker that was implanted in him had been recalled in connection with defective product concerns.

On July 25, 2006, Alexander filed this case against Defendants Boston Scientific Corporation ("BSC"), Guidant Subsidiary of Boston Scientific Corporation ("Guidant"), and St. Anthony's in the Circuit Court of St. Louis County, Missouri. It is undisputed that Alexander and St. Anthony's are both Missouri residents. Guidant is a citizen of Indiana and BSC is a citizen of Delaware and Massachusetts.

Alexander alleges that BSC and Guidant are liable for manufacturing and design defects and for the failure to warn patients of the alleged health risks and/or defects associated with certain Guidant implantable cardiac medical devices. Alexander alleges that St. Anthony's committed medical negligence because it knew or had reason to know that Alexander's Guidant device was potentially defective and because it did not advise Alexander or put Alexander on notice of these facts prior to implantation.

More specifically, Alexander alleges that:

[p]rior to the actual implant surgery, both Guidant Corporation's said and physically present employee/agent and St. Anthony's Medical Center nursing staff or a designated St. Anthony's Medical Center employee/agent had the duty to disclose to Plaintiff that the Guidant pacemaker to be implanted in Plaintiff's chest is potentially defective and that a recall had been issued for Guidant pacemakers, model 1291 in September 2005 and that there existed a known manufacturing/assembly defect such that some unspecified percentage of Guidant pacemakers, model 1291, are known to be dangerously defective.

4. Both Guidant Corporation's said employee/agent and St. Anthony's Medical Center's staff employees attending to Plaintiff on May 25, 2006 breached the duty to disclose to Plaintiff that some unspecified percentage of Guidant pacemakers, model 1291, are know[n] to be dangerously defective, that several persons have died in connection with Guidant pacemakers, and that hundreds of product liability law suits are pending against Guidant Corporation.

(Williams Aff., Ex. B at 3-4.)

On August 25, 2006, BSC and Guidant removed the case to the United States

District Court for the Eastern District of Missouri, Eastern Division, asserting that
complete diversity exists because Alexander improperly joined St. Anthony's to defeat
diversity jurisdiction. BSC and Guidant then filed a motion to stay all proceedings
pending transfer of Alexander's case to the District of Minnesota as part of MDL

No. 1708. The United States District Court for the Eastern District of Missouri granted
the motion to stay and on February 7, 2007, the case was formally transferred to the
District of Minnesota as part of MDL No. 1708.

On February 20, 2007, Alexander filed a Motion to Remand to St. Louis County Circuit Court, claiming that St. Anthony's is a proper defendant in the case and therefore complete diversity is lacking. On March 9, 2007, St. Anthony's filed a Motion to Dismiss, claiming that Alexander has failed to state a claim against St. Anthony's.

#### I. Motion to Remand

The party seeking removal and opposing remand bears the burden of establishing federal subject matter jurisdiction. *In re Bus. Men's Assurance Co. of Am.*, 992 F.2d 181, 183 (8th Cir. 1993). Generally, a state court action may only be removed if a federal district court would have original jurisdiction to hear the case. 28 U.S.C. § 1441(a).

Section 1441(a) provides in pertinent part:

<sup>[</sup>A]ny civil action brought in a state court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or defendants, to the district court of the United States.

<sup>28</sup> U.S.C. § 1441(a).

Where the action is based upon diversity jurisdiction, it is removable "only if none of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought." 28 U.S.C. § 1441(b). "In determining whether removal was proper, the removal statute is to be narrowly construed and all doubts about the propriety of federal jurisdiction are to be resolved against removal." *In re Potash Antitrust Litig.*, 866 F. Supp. 406, 410 (D. Minn. 1994). "If at any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case shall be remanded." 28 U.S.C. § 1447(c).

Alexander essentially argues that BCS and Guidant had no right to remove under 28 U.S.C. § 1441(a) because there is incomplete diversity of citizenship because St. Anthony's is a Missouri resident. Alexander therefore argues that because there is no original jurisdiction, under 28 U.S.C. § 1447(c) the case must be remanded.

Here, because St. Anthony's is a Missouri resident, the action on its face is not removable. Defendants assert, however, that removal was proper because Alexander fraudulently joined St. Anthony's to defeat diversity jurisdiction. Under the doctrine of fraudulent joinder, joinder of a party that is designed solely to deprive federal courts of jurisdiction is deemed fraudulent and does not prevent removal. *Anderson v. Home Ins.*Co., 724 F.2d 82, 84 (8th Cir. 1983). Fraudulent joinder does not require fraudulent intent; rather, fraudulent joinder exists if the plaintiff's claim against an in-state defendant has no chance of success. *Schwenn v. Sears, Roebuck & Co.*, 822 F. Supp. 1453, 1455 (D. Minn. 1993); see also Filla v. Norfolk S. Ry. Co., 336 F.3d 806, 809-10 (8th Cir. 2003) (stating that the Court must "determine whether there is a reasonable basis

for predicting that the state's law might impose liability against the defendant"); Wiles v. Capitol Indem. Corp., 280 F.3d 868, 870 (8th Cir. 2002) ("Joinder is fraudulent and removal is proper when there exists no reasonable basis in fact and law supporting a claim against the resident defendant."); Anderson, 724 F.2d at 84 ("Fraudulent joinder exists if, on the face of plaintiff's state court pleadings, no cause of action lies against the resident defendant."). The burden is on the defendants to establish that a party has been fraudulently joined. Schwenn, 822 F. Supp. at 1455.

Guidant and BSC contend that the Court should find fraudulent joinder because Alexander failed to plead a cause of action against St. Anthony's. St. Anthony's similarly asserts that complete diversity exists because Alexander failed to state a claim against St. Anthony's. Specifically, Defendants assert that Alexander failed to plead any facts showing that St. Anthony's received the September 22, 2005 recall letter, and even if St. Anthony's did receive the letter, the letter did not instruct physicians to cease implantation of Model 1291 devices or ask for their return. In addition, Defendants assert that the December 12, 2005 Advisory Update states that the devices distributed after the recall letter were not subject to the recall, and therefore the device implanted in Alexander, which was manufactured in December 2005, was not subject to a recall on the date it was implanted.<sup>2</sup>

The Court notes that the December 12, 2005 Advisory Update actually states that "Guidant has recently discontinued shipping from manufacturing facilities INSIGNIA and NEXUS devices susceptible to 'Failure Mode 2,'" and that "INSIGNIA and NEXUS devices currently being distributed by Guidant are not subject to either failure mode and therefore are not included in either recall." (Williams Aff. at Ex. D (emphasis added).)

(Footnote Continued on Next Page)

St. Anthony also asserts that it does not owe a duty to patients to report that the manufacturer of certain devices used in its facilities is a party to litigation regarding products that are not being used with that particular patient. And, St. Anthony asserts that because Alexander has not plead any facts demonstrating that anyone at St. Anthony's assumed a duty to inform him of risks associated with his device, contending that Missouri law requires such assumption, Alexander has failed to state a claim against St. Anthony's.<sup>3</sup>

Alexander, on the other hand, asserts that he has a cause of action against

St. Anthony's based on his allegations that St. Anthony's knew that model 1291

pacemakers were known to be dangerously defective by May 25, 2006, and knew that

Guidant had recalled model 1291 pacemakers eleven months prior to his implantation yet

continued to market the units. Alexander asserts that despite this knowledge,

St. Anthony's—acting through its employees/agents—selected a model 1291 Guidant

pacemaker to be implanted into Alexander. Alexander alleges that, prior to his

implantation, St. Anthony's concealed all of this information from him.

<sup>(</sup>Footnote Continued From Previous Page)

This does not necessarily indicate that the devices distributed after the September 22, 2005 letter were not subject to the recall, as the Advisory Update does not give specific dates as to when those specific devices were discontinued and as to when distribution stopped.

BSC and Guidant also assert that to the extent Alexander's claim against St. Anthony's was a strict liability claim, the claim is foreclosed under Missouri law. Because Alexander concedes that his claim is not a strict liability claim, the Court does not address the issue here.

Alexander asserts that his allegations are supported by the fact that Guidant issued a recall regarding the model 1291 pacemakers on September 22, 2005, Guidant issued a separate recall regarding the model 1291 pacemakers within thirty days of his implantation, and as of the date of his implantation, hundreds of product liability lawsuits involving Guidant pacemakers were pending in state and federal courts. In addition, Alexander asserts that because "[St. Anthony's] is in the business of implanting pacemakers and defibrillators and routinely does business with manufacturers and distributors of implantable cardiac devices," St. Anthony's "would certainly know the quality history and dependability rating of manufacturers selected by [St. Anthony's] to supply pacemakers for implantation by [St. Anthony's]." (Pl.'s Resp. in Opp'n to Def. St. Anthony's Medical Center's Mot. to Dismiss and to Def.'s Opp'n to Pl.'s Mot. to Remand to St. Louis County Circuit Court at 2.)

The Court acknowledges that Alexander is proceeding *pro se. Pro se* pleadings are liberally construed and are held to less stringent standards than formal pleadings drafted by lawyers. *See Martin v. Sargent*, 780 F.2d 1334, 1337 (8th Cir. 1985); *see also Estelle v. Gamble*, 429 U.S. 97, 106 (1976) (quoting *Haines v. Kerner*, 404 U.S. 519, 520 (1972) (per curiam) (stating *pro se* complaints are held to less stringent standards than formal pleadings drafted by lawyers). Although BSC and Guidant contend that St. Anthony's failure to warn claims are without factual basis because it was "factually impossible" for St. Anthony's to have disclosed to Alexander that his device was potentially defective, the Court finds that, at this juncture, fact issues preclude the Court from finding that there is no basis for liability.

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"[C]ontested issues of fact should be resolved in favor of the plaintiff." *Schwenn*, 822 F. Supp. at 1455. Alexander alleges in his Complaint, among other things, that "the medical center does business with Guidant Corporation on a regular basis and routinely invites Guidant Corporation employees/agents into its operating rooms during the implanting of Guidant pacemakers for programming purposes." (Williams Aff., Ex. B at 4-5.) At a minimum, Alexander has raised an issue as to whether St. Anthony's knew or had reason to know that Alexander's device was recalled and/or potentially defective in light of the publicity Guidant had received prior to Alexander's implantation regarding potentially defective devices.

"Joinder is fraudulent only where there is no reasonable basis in fact or colorable ground supporting the claim against the resident defendant, or where the plaintiff has no real intention of prosecuting the action against the resident defendant." *Schwenn*, 822 F. Supp. at 1455. Here, Alexander's pleadings do allege facts, which if true, have a chance of success. At a minimum, in light of the liberal pleading requirements, the Court cannot conclude that no valid claims are brought against St. Anthony's as a matter of well-settled law. In addition, there is no evidence that St. Anthony's was singled out to avoid federal diversity jurisdiction rather than to obtain full relief. Accordingly, Alexander's joinder of St. Anthony's cannot be deemed fraudulent. Therefore, the Court concludes that because St. Anthony's was joined as a defendant, it lacks subject matter jurisdiction over this action as it currently stands.

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#### Sever and Remand

To the extent the Court does find that St. Anthony's was not fraudulently joined, which the Court does find, BSC and Guidant alternatively request the Court to sever and remand Alexander's claims against St. Anthony's to state court and retain jurisdiction over Alexander's claims against BSC and Guidant. Specifically, BSC and Guidant assert that Alexander had fraudulently misjoined St. Anthony as a party, and therefore the claims against St. Anthony should be severed from the claims asserted against BSC and Guidant. BSC and Guidant contend that the claims arising out of St. Anthony's treatment do not arise out of the same transaction or occurrence as the claims against BSC and Guidant because the claims against St. Anthony's are based on medical negligence while the claims against BSC and Guidant are based on product liability. Alexander contends that his claims against St. Anthony's are not negated simply because his claims against BSC and Guidant are based on product liability. Alexander asserts that the Defendants' actions/inactions do arise out of the same transaction or occurrence.

The Federal Rules of Civil Procedure allow for permissive joinder of defendants as follows:

All persons . . . may be joined in one action as defendants if there is asserted against them jointly, severally, or in the alternative, any right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences and if any question of law or fact common to all defendants will arise in the action.

Fed. R. Civ. P. 20(b). If defendants have been misjoined for the failure to satisfy the conditions for permissive joinder under Rule 20(b), the Rules allow for severance of those defendants:

Misjoinder of parties is not ground for dismissal of an action. Parties may be dropped or added by order of the court on motion of any party or of its own initiative at any stage of the action and on such terms as are just. Any claim against a party may be severed and proceeded with separately.

Fed. R. Civ. P. 21.

Upon review of the applicable rules and the pleadings of the parties, the Court finds that St. Anthony's has been improperly joined in this case. The joinder of the malpractice claim against St. Anthony's with the other product liability claims was inappropriate because the claims do not both involve common questions of law or fact and assert joint, several, or alternative liability "arising out of the same transaction, occurrence, or series of transactions or occurrences." Fed. R. Civ. P. 20(b). Any liability that may be found against either BSC/Guidant or St. Anthony's would not be a basis for liability as to the other. However, separate liability as to each could be separately found.

This finding is consistent with how joinder has been interpreted in Missouri. The Missouri Supreme Court, for example, has rejected the propriety of joining defendants involved in successive accidents. *State ex rel. Jinkerson v. Koehr*, 826 S.W.2d 346, 348 (Mo. 1992) (en banc). There, the plaintiffs alleged they were seriously injured as a result of the successive negligent acts or omissions of the defendants "in combination" and that

The Missouri rule on permissive joinder is nearly identical to the federal rule and is identical in all relevant parts here. *See* Mo. R. Civ. P. 52.05.

the two accidents "were not separate and distinct but inseparable and indistinguishable thereby creating common liability among all of the named defendants." *Id.* at 346, 348. The supreme court held that joinder was not permitted under Mo. R. Civ. P. 52.05(a) because the cause of action arising out of the two accidents did not arise out the same transaction or occurrence. Instead, "[e]ach defendant [was] responsible for the injuries caused in the accident in which he or she was involved." *Id.* at 348. In light of *Jinkerson*, the Court finds that it likely that the state court would find that Alexander did not have a reasonable basis for joining St. Anthony's under state procedural law and that Alexander should sue St. Anthony's under a separate state action.

Although some courts faced with fraudulent misjoinder claims have required both a finding of misjoinder and a finding of a bad faith attempt to defeat diversity, other courts have refused to apply the "egregious" standard when considering misjoinder in the context of remand petitions. *See In re: Baycol Products Litig.*, MDL No. 1431 (MJD), Case. No. 03-2931, 2003 WL 22341303, at \*3 (D. Minn. 2003) (citing cases). The Eighth Circuit Court of Appeals has not addressed the issue.

Here, as the court in *Greene v. Wyeth* found, the Court "rejects the notion that Plaintiff[] ha[s] committed an egregious act or fraud upon the Court." 344 F. Supp. 2d 674, 685 (D. Nev. 2004). "[U]nder our dual court system[, if] a potential plaintiff has a choice between a state forum and a federal forum, it is his privilege to exercise that choice subject to legal limitations, and if he can avoid the federal forum by the device of *properly* joining a non[-]diverse defendant or a non[-]diverse co-plaintiff, he is free to do so." *Iowa Pub. Serv. Co. v. Med. Bow Coal Co.*, 556 F.2d 400, 406 (8th Cir. 1977)

(emphasis added). However, where a non-diverse party, such as St. Anthony's here, cannot be properly joined under the Federal Rules of Civil Procedure, other interests, such as the Defendants' statutory right of removal, prevail over that of permitting a plaintiff's choice of forum. *See Greene*, 344 F. Supp. 2d. at 685. Because the misjoinder of St. Anthony's would destroy complete diversity, and because the basis for the causes of action against St. Anthony's do not arise from the same transaction and occurrences as those in the causes of action against the other Defendants, the Court will sever the action against St. Anthony's so as to preserve BSC and Guidant's right to removal in the remaining action and to preserve the interests of judicial expediency and justice.

#### **II.** Motion to Dismiss

Because the Court concludes that the action against St. Anthony's shall be severed and remanded from the lawsuit, the Court denies St. Anthony's Motion to Dismiss as moot.

#### IT IS HEREBY ORDERED that:

1. Plaintiff Alexander's Motion for Remand to St. Louis County Circuit Court (MDL No. 05-1708 (DWF/AJB), Doc. No. 1258; Civil No. 07-1129 (DWF/AJB), Doc. No. 3) is **GRANTED** as to Defendant St. Anthony's Medical Center but **DENIED** as to all remaining Defendants. The Court Orders that all claims against Defendant St. Anthony's Medical Center are **SEVERED** and **REMANDED** to St. Louis County Circuit Court.

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Defendant St. Anthony's Motion to Dismiss (MDL No. 05-1708 2. (DWF/AJB), Doc. No. 1308; Civil No. 07-1129 (DWF/AJB), Doc. No. 9) is **DENIED** AS MOOT WITHOUT PREJUDICE.

Dated: June 4, 2007

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s/Donovan W. Frank DONOVAN W. FRANK Judge of United States District Court

## **EXHIBIT**

#### VERDICTS IN AEMLD CASES

\$2,000,000 (\$800,000 Compensatory, \$1,200,000 Punitive)	<u>Pierce v. Illinois Tool Works, Inc.</u> , 2005 WL 4677813 (Ala. Cir. Ct., Dekalb County, Sept. 15, 2005) (products liability action by plaintiff who suffered destroyed vision when nail gun inadvertently fired nail into the worker's eye)
\$800,000 (\$400,000 to each plaintiff)	Gurley v. A.L. Lee Corp., 2005 WL 1639477 (Ala. Cir. Ct., Tuscaloosa County, Jan. 26, 2005) (products liability action by plaintiffs who suffered third degree burns when air compressor they plugged in produced electrical arc)
\$2,500,000	Shaffer v. Am. Lifts, 2004 WL 3201058 (Ala. Cir. Ct., Marion County, Nov. 17, 2004) (wrongful death case based on products liability claim against scissor lift manufacturer arising out of lift collapse)
\$3,500,000	Nall v. Altec Indus., Inc., 2005 WL 4774224 (Ala. Cir. Ct., Mobile County, Sept. 29, 2005) (products liability action by plaintiff who suffered ruptured spleen when aerial lift collapsed to ground with plaintiff inside)
\$4,500,000	Sanders v. Inductotherm Indus., 2004 WL 3201162 (Ala. Cir. Ct., Jefferson County, Oct. 2004) (products liability and wrongful death claim arising out of furnace explosion)
\$950,000	Castleberry v. Cantrell Mach. Co., 2004 WL 3201180 (Ala. Cir. Ct., Blount County, Sept. 2, 2004) (products liability action by a woman whose hand was injured by a chicken heart and liver harvesting machine)
\$50,000,000 (Original Verdict)	Mack Trucks, Inc. v. Witherspoon, 867 So. 2d 307 (Ala. 2003) (products liability case arising out of a tractor-trailer rollover)
\$12,000,000 (\$6,000,000 Compensatory, \$6,000,000 Punitive)	Morgan v. ProTech Industries, 2003 WL 23111870 (Ala. Cir. Ct., Lamar County, Aug. 29, 2003) (wrongful death case based on products liability claim against truck manufacturer arising out of rollover and absence of cab guard on logging truck)
\$7,000,000	<u>Daniel v. Snap Products</u> , 2003 WL 23111815 (Ala. Cir. Ct., Baldwin County, May 28, 2003) (wrongful death case based on products liability claim against manufacture of tire repair product after treated tire exploded)
\$4,168,500 (\$1,068,500 Compensatory, \$3,100,000 Punitive)	McClain, et al. v. Metabolife Intl., Inc., 259 F. Supp. 2d 1225 (N.D. Ala. 2002) (products liability action by four plaintiffs who suffered cardiac symptoms after using ephedra-based diet drug) (reversed on appeal, 401 F.3d 1233 (11 <sup>th</sup> Cir. 2005), and remanded for a new trial)
\$960,000 (\$25,000 over and above \$935,000 in pro tanto settlements)	Hannah v. Gregg Bland & Berry, 2002 WL 32169853 (Ala. Cir. Ct., Colbert County, Oct. 25, 2002) (wrongful death case arising out of fatal crush injury in industrial belt equipment)
\$122,000,000 (\$22,000,000 Compensatory, \$100,000,000	Jernigan v. General Motors Corp., Bullock County (May 3, 2002) (products liability case arising out of collapse of Oldsmobile passenger compartment) (reversed on appeal, 883 So.2d 646 (Ala. 2003), and remanded for new trial)

Punitive)	
\$510,000 (Compensatory) \$10,000,000 (Punitive)	Hobart Corporation v. Scottie W. Scoggins, 776 So.2d 56 (Ala. 2000) (products liability action by a man who was injured while using a meat saw manufactured by Hobart)
\$3,000,000 (\$2,500,000 (Compensatory \$500,000 Punitive)	Cessna Aircraft Company v. Robert Trzcinski, 682 So. 2d 17 (Ala. 1996) (products liability action by a man who was injured in an airplane crash due to a defective shoulder harness)
\$1,000,000 (Original verdict \$825,000)	<u>Uniroyal Goodrich Tire Company v. Jackie Darryl Hall</u> , 681 So. 2d 126 (Ala. 1996) (products liability action by a man who was injured when wheel rim exploded)
\$1,225,000	Ford Motor Company v. June Burdeshaw, 661 So. 2d 236 (Ala. 1995) (wrongful death case brought against truck manufacturer after decedent was killed by a truck's transmission slipping out of neutral and crushing him)
\$13,000,000	General Motors Corporation v. Pamela L. Saint, 646 So. 2d 564 (Ala. 1994) (products liability action by a woman who was injured due to a defective seat belt)
\$250,000 (\$100,000 Compensatory, \$150,000 Punitive)	<u>Flagstar Enterprises, Inc. v. Maureen Davis</u> , 709 So. 2d 1132 (Ala. 1998) (products liability action by a woman who found human blood in styrofoam package containing biscuit gravy)
\$250,000	Caterpillar, Inc. v. Hightower, 605 So. 2d 1193 (Ala. 1992) (product liability action brought by a man who was injured by a broken tree trunk while handling machinery during logging operation)
\$115,000	Banner Welders, Inc. v. Knighton, 425 So. 2d 441 (Ala. 1982) (product liability claim against manufacture for personal injuries received on shuttle welder)
\$6,500,000	Sears, Roebuck & Co. v. Harris, 630 So. 2d 1018 (Ala. 1993) (wrongful death case based on product liability claims against manufacturer and retailer of gas water heater that caused carbon monoxide poisoning)
\$7,500,000	General Motors Corp. v. Johnson, 592 So. 2d 1054 (Ala. 1992) (wrongful death case based on product liability claim where child was killed in automobile accident)
\$5,000,000	Industrial Chem. & Fiberglass Corp. v. Chandler, 547 So. 2d 812 (Ala. 1989) (widows of two workers killed in industrial accident brought wrongful death action against distributor of cleaning substances that ignited and caused death of workers)